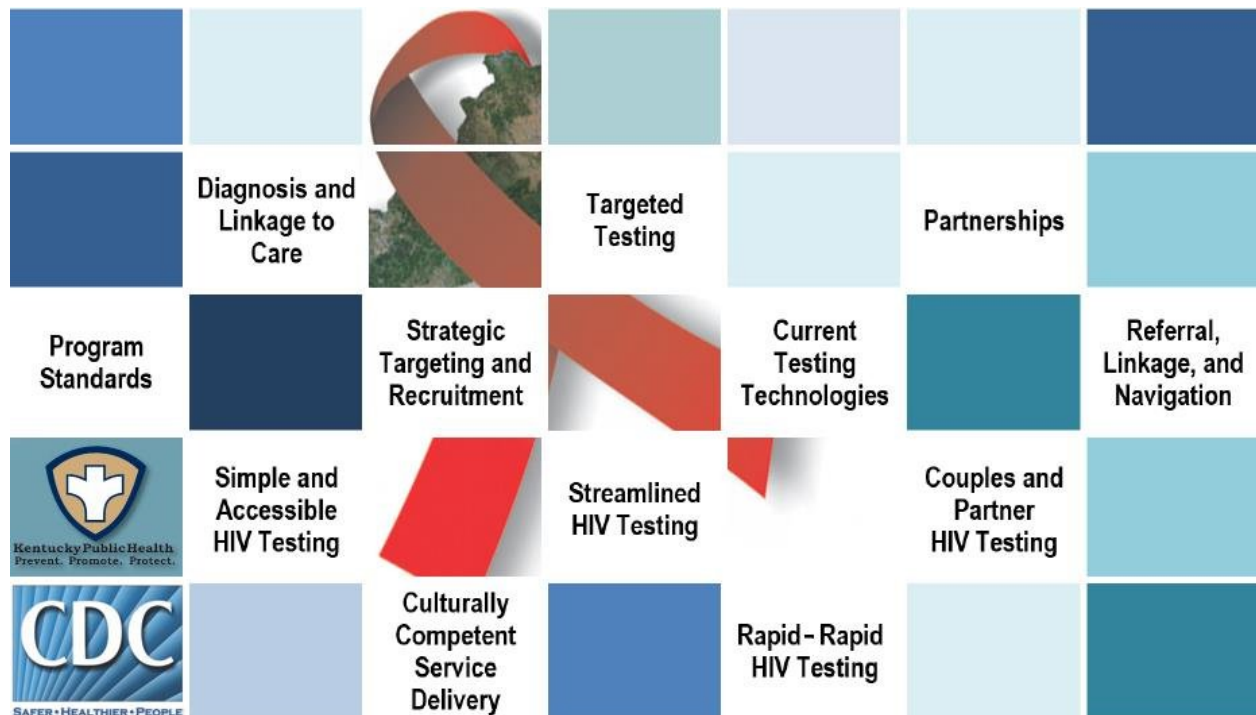


# Implementing Rapid-Rapid HIV Testing in Nonclinical Settings

## A Guide for Kentucky HIV Testing Providers



Updated December 2017

Program guidance intended for use by HIV testing providers in nonclinical settings funded by the Kentucky Department for Public Health. HIV testing providers not funded by Kentucky may also find this information useful. This guidance is adapted from the CDC's "Implementing HIV Testing in Nonclinical Settings."

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The *Implementing HIV Testing in Nonclinical Settings: A Guide for HIV Testing Providers* (herein after referred to as Implementation Guide) was created to support the implementation of HIV testing services in nonclinical settings. The Implementation Guide was developed by the U.S. Centers for Disease Control and Prevention, Division of HIV/AIDS Prevention, Capacity Building Branch. Many persons supported the Capacity Building Branch and contributed to the development of this document and previous drafts of the Implementation Guide. They are listed in alphabetical order below.

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## ACRONYMS

AIDS	acquired immune deficiency syndrome	KDPH	Kentucky Department for Public Health
ART	antiretroviral therapy	M&E	monitoring and evaluation
ARTAS	antiretroviral treatment and access to services	MOA	memorandum of agreement
CBA	capacity building assistance	MSM	gay, bisexual, and other men who have sex with men
CBO	community-based organization	NAT	nucleic acid test
CDC	U.S. Centers for Disease Control and Prevention	NHAS	National HIV/AIDS Strategy
CHTC	couples HIV testing and counseling	NHM&E	National HIV Prevention Monitoring and Evaluation
CLIA	Clinical Laboratory Improvement Amendments	nPEP	nonoccupational postexposure prophylaxis
CPN	CBA providers network	OSHA	Occupational Safety and Health Administration
CRIS	CBA Request Information System	PEP	postexposure prophylaxis
DIS	disease intervention specialist	PrEP	preexposure prophylaxis
EBI	evidence-based intervention	PS	partner services
FDA	Food and Drug Administration	PWID	persons who inject drugs
HAART	highly active antiretroviral therapy	QA	quality assurance
HCO	health care organization	QC	quality control
HD	health department	RNA	ribonucleic acid
HIP	high-impact prevention	RTA	rapid-rapid testing algorithm
HIPAA	Health Insurance Portability and Accountability Act	SNS	social networking strategy
HIV	human immunodeficiency virus	STD	sexually transmitted disease
HNS	HIV navigation services	TB	tuberculosis

## EXECUTIVE SUMMARY

For years now, the Kentucky Department for Public (KDPH) has supported a number of HIV test sites in all 120 counties with rapid HIV antibody tests. Without these rapid tests (which provide onsite screening results within 15-20 minutes), clients must wait weeks to receive their results from a laboratory. Most clients do not return to hear of their lab results. As advantageous as it has been to use rapid tests, those with reactive results still required follow-up confirmatory testing that often involved referring the client to another agency for a blood draw, and always involves sending a specimen to an offsite laboratory for confirmatory testing. This approach delays the provision of immediate HIV treatment, which is now recommended for all people with HIV (regardless of disease progression).

The Centers for Disease Control and Prevention (CDC) has provided an approved testing algorithm (set of steps) that eliminates the delay caused by requiring HIV confirmation prior to linking the client to an HIV care provider. The following KDPH policy applies the CDC algorithm, which calls for the use of two rapid HIV tests of different brands used in tandem. When an initial (more sensitive) rapid HIV test is reactive, the client can immediately be tested onsite with a second less sensitive rapid test. If both types of rapid tests are reactive, the client is almost certainly infected with HIV and should be immediately linked to an HIV care provider. This provider will do any necessary confirmatory testing, viral load testing, genotype testing, etc. required to initiate HIV treatment. This “rapid-rapid testing algorithm” (RTA) ensures that all clients can discover their HIV antibody status and take immediate steps to treat the infection. Effective treatment for HIV drastically lowers the chance of transmission and progression of disease, so the earlier treatment begins, the better.

### KEY POINTS – RAPID-RAPID ALGORITHM

In short, nonclinical Kentucky HIV test sites can now test all clients with SURE CHECK (a more sensitive fingerstick rapid HIV antibody test). Those with negative SURE CHECK tests are antibody-negative and no additional antibody testing would be required at that time. Those with reactive results from the SURE CHECK test can be tested immediately with an additional rapid OraQuick test (a slightly less sensitive fingerstick or oral swab HIV antibody test). Clients receiving reactive results from both rapid tests (SURE CHECK first, then OraQuick) are almost certainly infected with HIV and can be linked to an HIV care provider without waiting days or weeks for a confirmatory test.

In cases where the initial SURE CHECK test is reactive, but the follow up OraQuick is nonreactive, submit a specimen to laboratory or refer to a clinical provider for follow-up testing.

This testing approach is for nonclinical settings such as harm reduction/syringe exchange programs, community-based organizations, outreach testing efforts, and field testing. This algorithm has NOT been approved for use in clinical settings.

Increased responsibilities for HIV test sites will include training and quality assurance measures for both SURE CHECK and OraQuick instead of just one or the other. KDPH will provide its supported HIV test sites with both tests, training, and supplies for RTA. The advantages to test sites include same-day referrals to HIV care providers ... eliminating the need for any additional appointment and follow-up to counsel the client on confirmatory test results.

## KEY SUMMARY POINTS

1. **KDPH and CDC support 2 primary models of HIV testing**—routine testing in clinical settings and targeted testing in nonclinical settings; this Implementation Guide is intended to be used by HIV testing providers in nonclinical settings.
2. **HIV testing remains a critical element of the care continuum**—a key goal of HIV testing services is to diagnose HIV infection in persons who did not previously know their HIV status and to link them with follow-up care, treatment, and prevention services.
3. Agencies should **adhere to program standards**, including local and state public health policies and laws, to ensure they deliver high-quality HIV testing services that are culturally competent and linguistically appropriate.
4. HIV testing in nonclinical settings should be **simple, accessible, and straightforward**. Minimize client barriers and focus on delivering HIV test results and on supporting clients to access follow-up HIV care, treatment, and prevention services as indicated.
5. To reach populations at high risk for HIV infection, sites should **employ strategic targeting and recruitment efforts, establish targets for key program indicators, and monitor service delivery** to ensure targeted testing is achieving program goals.
6. To provide the most accurate results to clients, sites should **use HIV testing technologies that are the most sensitive, cost-effective, and feasible for use at their agency**. Establishing relationships with facilities offering laboratory-based HIV testing is important for referring clients who may have acute HIV infection.
7. **CDC no longer supports extensive pretest and posttest counseling** as part of the HIV testing event. Instead, CDC supports a streamlined model of HIV testing that includes delivering key information, conducting the HIV test, completing brief risk screening, providing test results, and delivering referrals tailored to the client's specific risk.
8. Sites should consider **offering HIV testing services for couples or partnered relationships** to (a) attract high-risk clients who are not otherwise testing and (b) identify HIV-discordant couples and previously undiagnosed HIV-positive clients. Specific training is required before attempting this.
9. To facilitate referral and linkage, agencies should **establish partnerships with organizations that offer essential follow-up services**, including clinics that offer HIV care and treatment, PrEP, and nPEP. Agencies should develop and implement protocols to help clients navigate the health care system and access these essential services as needed.

## Chapter 1

### INTRODUCTION

*Implementing HIV Testing in Nonclinical Settings: a Guide for HIV Testing Providers* (hereafter referred to as Implementation Guide) provides practical considerations for human immunodeficiency virus (HIV) testing in nonclinical testing sites. It is meant to be used by KDPH-funded HIV testing providers, and may also be useful for providers who are not directly funded by the state or CDC. This Implementation Guide is intended as an orientation tool for HIV testing providers, so that they have one comprehensive but easy-to-read source of important information that will help them provide high-quality HIV testing services to their clients. Because this document is program guidance, and not guidelines, it was not vetted through CDC's rigorous guidelines development process. This document was informed by scientific evidence and best practices, and references relevant literature.

### Purpose

The purpose of this Implementation Guide is to familiarize HIV testing providers working in State-funded nonclinical settings with key programmatic issues and updates that impact HIV testing service delivery. This includes, but is not limited to, reinforcing language about targeting and recruitment for HIV testing, advances in HIV testing technologies and algorithms, new protocols for conducting HIV testing with abbreviated prevention counseling, and with additional training – the inclusion of couples HIV testing. HIV testing providers who are aware of these issues are more likely to provide high-quality HIV testing services to their clients.

### Rationale

The rationale for developing this Implementation Guide was to update key programmatic issues for HIV testing in nonclinical settings that have not been addressed since the release of *Revised Guidelines for HIV Counseling, Testing, and Referral*<sup>1</sup> in 2001. Additionally, scientific and programmatic advances in HIV care, treatment, and prevention warranted revisiting and updating previous recommendations. Some updates were included in the comprehensive *Planning and Implementing HIV Testing and Linkage Programs in Non-clinical Settings: a Guide for Program Managers*<sup>2</sup> (hereafter referred to as Program Manager Guide). However, the Program Manager Guide focused on planning an HIV testing program, and this Implementation Guide focuses on conducting HIV testing with clients. Therefore, the primary target audience for this document is HIV testing providers and not necessarily HIV program managers, although program managers will also find this information useful.

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<sup>1</sup> CDC. Revised guidelines for HIV counseling, testing, and referral. *MMWR* 2001;50(RR-19):1-62.

<sup>2</sup> ICF Macro, Inc. Planning and implementing HIV testing and linkage programs in non-clinical settings: a guide for program managers. [https://effectiveinterventions.cdc.gov/docs/default-source/public-health-strategies-docs/HIVTestingImplementationGuide\\_Final.pdf](https://effectiveinterventions.cdc.gov/docs/default-source/public-health-strategies-docs/HIVTestingImplementationGuide_Final.pdf) Published 2012. Accessed March 24, 2016.

Although this Implementation Guide is consistent with many aspects of the aforementioned guidelines and Program Manager Guide (e.g., provision of voluntary, confidential HIV testing; need for obtaining informed consent; providing client-centered services; making referrals and linkages based on test results), there are also several updates. These updates include:

- Addressing HIV diagnosis as the first step in the HIV care continuum
- Emphasizing the use of novel strategies for targeting and recruitment of high-risk populations, including partners of people living with HIV
- Discussing advances in HIV testing technologies, including "rapid-rapid" HIV test algorithms (RTA)
- Separating prevention counseling from the HIV test event and streamlining the protocol for HIV testing
- Highlighting couple and partner HIV testing and counseling, or "Testing Together," as an opportunity to ensure mutual disclosure of HIV status and improve prevention outcomes
- Emphasizing the importance of linking high-risk HIV-negative clients with prevention services, including nonoccupational postexposure prophylaxis (nPEP) and preexposure prophylaxis (PrEP)
- Focusing on partnerships between nonclinical and clinical sites to enhance linkage for persons living with HIV to access care and treatment within 30 days after diagnosis

## Intended Audience

This Implementation Guide is intended for HIV testing providers who work in nonclinical settings, including any person who provides HIV testing services or oversees the provision of HIV testing services. It is meant to be used by KDPH-funded HIV testing providers and may also be useful for providers that are not directly funded by KDPH.

## Background

CDC recommends that all adolescents and adults get tested for HIV at least once as a routine part of medical care. CDC also recommends more frequent testing (at least annually) for men who have sex with men (MSM), persons who inject drugs (PWID), and other persons at high risk for HIV infection.<sup>1</sup> Significant advances in HIV testing have been made since the Food and Drug Administration (FDA) approved the first commercial HIV blood test more than 30 years ago, and it is now easier than ever to get tested for HIV. Testing technologies have improved, same-day results are available, testing venues are diverse and readily accessible, information about the importance of testing is clearer and more focused on client risk factors, and testing has become routine for many providers and clients. Additionally, testing is no longer something that has to be done alone—couples and sex partners can come in and get an HIV test together, supporting one another with a future-focused discussion of joint risk concerns and accessing follow-up services based on their test results and relationship status (note that couples testing requires additional training). The availability of antiretroviral therapy (ART) and, more recently, PrEP have provided new incentives for people to be tested, to take steps to keep themselves and their partners healthy, and to prevent new infections.

Despite these successes, of the 1.2 million Americans estimated to be living with HIV at the end of 2012, more than 156,000 did not know their HIV status (Figure 1).<sup>3</sup> This is significant because more than 30% of new HIV transmissions in the United States occur from persons who are HIV-infected but undiagnosed,<sup>4</sup> which reinforces the importance of increasing knowledge of HIV status through testing and of linkage to medical care as the first step on the HIV care continuum.<sup>5</sup>

Among persons whose HIV infection was diagnosed during 2013, 73% were linked to HIV medical care within 1 month after diagnosis and 82% were linked to care within 3 months.<sup>6</sup> Retaining these persons in care, however, is a challenge; only 53.9% of persons whose HIV infection had been diagnosed by year-end 2011 and who were alive at the end of 2012 had received HIV medical care during the first 4 months of 2012<sup>7</sup> (Figure 1). HIV testing programs have made strides in strengthening linkage to HIV medical care following diagnosis, but additional efforts are needed to reach the National HIV/AIDS Strategy for the United States (NHAS) goal of linking 85% of persons with newly diagnosed infection to HIV medical care within one month of diagnosis<sup>7</sup> and to retain these persons in care. Even though linkage and retention (or reengagement in care) usually happens after HIV testing, HIV testing staff should be aware of the importance of medical care for persons living with HIV infection and of their role in patient navigation. Presently, 61% of new transmissions occur from persons who are diagnosed but not retained in medical care; increased attention should be paid to this population.<sup>5</sup>

<sup>3</sup> CDC. Monitoring selected national HIV prevention and care objectives by using HIV surveillance data—United States and 6 dependent areas-2013. *HIV Surveillance Supplemental Report* 2015;20(No. 2). <http://www.cdc.gov/hiv/library/reports/surveillance/>. Published July 2015. Accessed March 24, 2016.

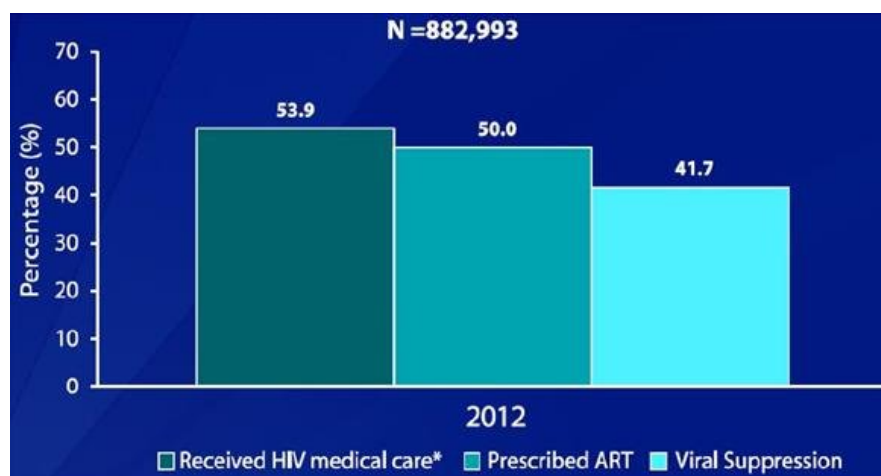
<sup>4</sup> Skarbinski J, Rosenberg E, Paz-Bailey G, et al. Human immunodeficiency virus transmission at each step of the care continuum in the United States. *JAMA Intern Med* 2015;175(4):588-596. doi:10.1001/jamainternmed.2014.8180. <http://www.ncbi.nlm.nih.gov/pubmed/25706928>. Accessed March 24, 2016.

<sup>5</sup> CDC. Understanding the HIV care continuum. [http://www.cdc.gov/hiv/pdf/DHAP\\_Continuum.pdf](http://www.cdc.gov/hiv/pdf/DHAP_Continuum.pdf). Published December 2014. Accessed March 24, 2016.

<sup>6</sup> CDC. Monitoring selected national HIV prevention and care objectives by using HIV surveillance data—United States and 6 dependent areas-2013. *HIV Surveillance Supplemental Report* 2015;20(No. 2). <http://www.cdc.gov/hiv/library/reports/surveillance/>. Published July 2015. Accessed March 24, 2016.

<sup>7</sup> White House Office of National AIDS Policy. National HIV/AIDS strategy for the United States: updated to 2020. <https://www.aids.gov/federal-resources/national-hiv-aids-strategy/nhas-update.pdf>. Published July 2015. Accessed March 24, 2016.

**Figure 1. Persons living with diagnosed HIV infection, 2012—Select HIV care continuum outcomes, United States and Puerto Rico**



**Source:** CDC. HIV care continuum for the United States and Puerto Rico. [http://www.cdc.gov/hiv/pdf/Continuum\\_Surveillance.pdf](http://www.cdc.gov/hiv/pdf/Continuum_Surveillance.pdf). Published July 2015. Accessed March 24, 2016.

**National HIV Surveillance System:** Estimated number of persons aged M3 years living with diagnosed or undiagnosed HIV infection (prevalence) in the United States at the end of 2012. The estimated number of persons with diagnosed HIV infection was calculated as part of the overall prevalence estimate.

**Medical Monitoring Project:** Estimated number of persons aged M8 years who received HIV medical care during January to April of 2012, were prescribed ART, or whose most recent VL in the previous year was undetectable or <200 copies/mL—United States and Puerto Rico.

## Vision

The nation's HIV prevention efforts are guided by the recognition that if everyone with HIV was aware of their infection and receiving the treatment they need, HIV infections in the United States would be greatly reduced. This is a key tenet of NHAS,<sup>8</sup> which includes several specific goals and indicators related to early HIV diagnosis and effective care, including reducing new HIV infections, improving access to care and health outcomes, reducing HIV-related health disparities, and achieving a more coordinated response:

- Increase the percentage of people living with HIV who know their status to at least 90%
- Reduce the number of new diagnoses by at least 25%
- Increase the percentage of persons with newly diagnosed infection linked to HIV medical care within one month of their HIV diagnosis to at least 85%
- Increase the percentage of persons with diagnosed HIV infection who are retained in HIV medical care to at least 90%
- Increase the percentage of persons with diagnosed HIV infection who are virally suppressed to at least 80%

<sup>8</sup> White House Office of National AIDS Policy. National HIV/AIDS strategy for the United States: updated to 2020. <https://www.aids.gov/federal-resources/national-hiv-aids-strategy/nhas-update.pdf>. Published July 2015. Accessed March 24, 2016.

To achieve these goals, CDC and its partners are pursuing the high-impact HIV prevention (HIP) approach,<sup>9</sup> which aims to achieve the greatest possible reductions in HIV infections by using a combination of evidence-based, cost-effective, and scalable strategies and interventions, such as HIV testing, linkage to HIV care for persons with newly diagnosed HIV infection, and reengagement in care for persons diagnosed but not currently in care. In accordance with NHAS and the HIP approach, resources are targeted to populations and regions that are most heavily affected by HIV, where they have the greatest potential to diagnose new HIV infections, link persons with effective HIV care and prevention services, and subsequently reduce new HIV infections.

## Defining Nonclinical Settings

KDPH and CDC supports 2 primary models of HIV testing: (1) routine testing in clinical settings, and (2) targeted testing in nonclinical settings. Although more HIV tests are conducted in clinical settings than in nonclinical settings, persons at high risk for HIV infection may not access health care services, and so it is important to utilize both strategies. This Implementation Guide is intended for the targeted testing in nonclinical settings, but may also be useful for HIV testing providers in clinical settings.

For the purposes of this Implementation Guide, nonclinical settings are sites where medical, diagnostic, and/or treatment services are not routinely provided, but where select diagnostic services, such as HIV testing, are offered.<sup>10</sup> Increasingly, agencies are beginning to offer clinical services within nonclinical settings, making this distinction a bit blurred. Still, a key feature of nonclinical settings is their location within the community—whether at fixed venues, outreach sites, or in a person's home, nonclinical settings are easily accessible and comfortable for populations who might not access medical services regularly. They typically provide same-day rapid HIV testing, they might offer other HIV prevention services such as structural or behavioral interventions and social services, and they conduct recruitment services to get high-risk populations in for targeted HIV testing.

Examples of nonclinical settings where HIV testing may be offered include, but are not limited to, community-based organizations (CBOs), mobile testing units, churches, bathhouses, parks, shelters, syringe services programs, health-related storefronts, homes, and other social service organizations. Agencies may choose to provide HIV testing services at multiple venue types to offer a diverse range of options, to better identify high-risk clients, and to meet the needs of the populations they serve.

Some health departments might be considered nonclinical settings and offer targeted HIV testing, while others offer clinical services and routine HIV testing. Furthermore, some health care organizations (HCOs) might provide a blend of routine and targeted HIV testing, even though they are considered clinical settings. This demonstrates the complexity of distinguishing between clinical and nonclinical settings.

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<sup>9</sup> CDC. High-impact HIV prevention: CDC's approach to reducing HIV infections in the United States. <http://www.cdc.gov/hiv/policies/hip.html>. Updated April 2013. Accessed March 24, 2016.

<sup>10</sup> ICF Macro, Inc. Planning and implementing HIV testing and linkage programs in non-clinical settings: a guide for program managers. [https://effectiveinterventions.cdc.gov/docs/default-source/public-health-strategies-docs/HIVTestingImplementationGuide\\_Final.pdf](https://effectiveinterventions.cdc.gov/docs/default-source/public-health-strategies-docs/HIVTestingImplementationGuide_Final.pdf). Published 2012. Accessed March 24, 2016.

## Using the Guide

This guide follows state public health policies and laws. Elements may also be adapted by local health departments for incorporation into updated local guidance, policies, and training materials. This guide does not replace HIV testing training for new staff, but it can be used as an orientation tool for new staff or as a refresher document for existing staff. KDPH-funded HIV testing providers should incorporate the concepts of this Implementation Guide into their nonclinical HIV testing programs and may address questions about the Implementation Guide to KDPH, or CDC subject matter experts. Also, CDC project officers, CBA providers, and local agency management may be able to answer questions, or may be helpful in referring questions to the appropriate subject matter experts. HIV testing providers not funded directly by KDPH may also find this information useful.

## Chapter 2

### PROGRAM PRINCIPLES AND STANDARDS

HIV testing programs must strive to provide high-quality services to best meet the needs of their clients and achieve their program objectives. There are certain principles and standards that should be met by all HIV testing programs in order to provide high-quality services. This chapter reviews these principles and standards, and provides links for accessing more information.

#### Guiding Principles

Staff conducting HIV testing should be trained in accordance with state and local requirements before providing services to clients.

The following principles guide the provision of HIV testing in nonclinical settings, and HIV testing providers should ensure that these are met:

1. HIV testing is **voluntary**; clients have elected to be tested of their own accord, and they are not coerced or forced to be tested. Clients have the right to decline services.
2. Clients give their expressed **informed consent** to be tested; they clearly understand basic information about HIV and HIV testing, and they provide verbal or written agreement to be tested for HIV.
3. HIV testing can be either **confidential** (name is given) or **anonymous** (name is not given); although confidential testing is preferred for facilitating linkage to care for newly diagnosed HIV-positive clients, some clients may only test if they can do so anonymously. Clients should understand the benefits of confidential testing compared to anonymous testing, including what measures are in place to protect their confidentiality, how their personally identifiable information will be protected, and who will know their test results (e.g., the local health department if the results are HIV-positive). For more information or to determine if anonymous testing is an option for your clients, consult with your supervisor and/or review state and local regulations.
4. HIV testing services should be **client-centered**; that is, services should be focused on the client's concerns and situation. Services should also be **culturally competent** with respect to race, ethnicity, gender, sexual orientation, age, language, literacy, relationship status, and other relevant factors.
5. All clients testing HIV-positive should be referred and **linked to care**, and these linkages should be tracked to ensure timely linkage and successful enrollment in care. More information on linkage, referral, and navigation services can be found in Chapter 7.

#### Special circumstances for consent

- KRS 214.185 allows for minors in Kentucky to give their own consent for HIV testing without the consent of or notification to the parent, parents, or guardian of such minor patient, or to any other person having custody of such minor patient.
- Agencies should also establish sobriety protocols to help counselors understand what to do if clients are under the influence of drugs, medication, or alcohol. If you have reason to believe that your client is intoxicated or not of sound mind, you may need to ask a supervisor or other colleague for assistance.
- Persons who have a mental health disorder may not be able to give their own consent for HIV testing. State laws may require permission from the person's legally authorized representatives.

## Ethical Standards

Agencies should establish an ethical code of conduct for their HIV testing services, which should be read and understood by all testing providers. This code of conduct should clarify that HIV testing providers should not use or be under the influence of alcohol or drugs while on duty; have sex with clients; exchange money with clients; or engage in other inappropriate behavior with clients. Agencies should establish and enforce these boundaries to protect their staff and their clients, and to ensure clients receive high-quality HIV testing services.

## Use Best Possible Technologies and Approach

Because one of the goals of HIV testing programs is to identify HIV infection as early as possible after exposure, programs should use testing technologies and specimens that allow for early detection. If possible, persons at highest risk should be tested for acute infection. In general, the tests used for this will be antigen/antibody combination tests used with blood specimens collected from the vein. However, it is not always feasible to have someone trained in collecting blood from a vein at nonclinical HIV testing sites, and so blood collected from a fingerstick is often used.<sup>11</sup> Blood (whole blood, serum, or plasma) is the preferred specimen for HIV testing because tests conducted with blood are more sensitive for early infection than tests conducted with oral fluid.<sup>12,13</sup> If an organization must use oral fluid for testing, it is important that clients and HIV testing providers understand the limitations.

## Preparing the HIV Testing Environment

HIV testing should be conducted in a private location where client confidentiality can be ensured and where a specimen can be collected safely and without risk of contamination. Some recommendations for establishing an ideal HIV testing environment include:

1. **Room/testing space:** Providers should ensure that the testing space has enough room and seating for all clients to feel comfortable and confident in their HIV testing experience.
2. **Lighting:** There should be enough light to allow providers to perform the test and read results accurately.
3. **Temperature:** Rapid HIV tests should be stored, transported, and conducted within specific temperature ranges specified by the manufacturer. HIV testing providers should check the package inserts to ensure they are adhering to these temperature specifications.
4. **Surface area:** Rapid HIV tests must be performed on a clean and level surface. HIV testing supplies and controls should be well organized, and no food or drink should be consumed near the testing area.

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<sup>11</sup> CDC. HIV Basics: Testing. <http://www.cdc.gov/hiv/basics/testing.html>. Updated April 2015. Accessed March 24, 2016.

<sup>12</sup> Delaney KP, Branson BM, Uniyal A, et al. Evaluation of the performance characteristics of 6 rapid HIV antibody tests. *Clin Infect Dis* 2011;52(2):257-63.

<sup>13</sup> Stekler JD, O'Neal JD, Lane A, et al. Relative accuracy of serum, whole blood, and oral fluid HIV tests among Seattle men who have sex with men. *Clin Virol* 2013;58(Suppl 1):e119-22.

5. Storage and disposal: Most rapid HIV tests can be stored at room temperature below 30°C/86°F. However, most controls used for quality assurance and quality control procedures must be stored in a refrigerator with temperature controls. HIV testing providers should maintain an inventory of testing supplies, including lot numbers, date of receipt, storage temperatures, expiration dates, and dates of use. Discard opened reagents after the manufacturer's expiration date, and do not use reagents from kits with different lot numbers interchangeably.
6. Equipment: Laboratory-based tests may require refrigeration of specimens. Refrigerators should have temperature controls, should only be used for the storage of samples and/or testing supplies, and should be labeled as such. A centrifuge will also be needed to prepare laboratory samples for testing.
7. Prevention Materials: Condoms, lubricants, and educational materials should be made available to clients in the HIV testing room as well as in the waiting area (or on display if at an outreach or community venue).
8. Supplies: Staff should have all the supplies, materials, and reference information necessary to provide HIV testing and linkage to care services, including data forms and testing logs; testing supplies and equipment; prevention and educational materials; referral and resource information; and client satisfaction or feedback questionnaires.

A detailed Outreach Testing Supplies and Materials Checklist is provided in the Program Manager Guide (see Program Manager Guide, Appendix D, Template 7).

## Policies and Legal Considerations

HIV testing providers should understand and provide services in accordance with their agency policies and state and local policies and laws. The policies and laws providers should be familiar with include, but are not limited to:

- Authorization for agencies provide HIV testing
- Provider training and certification to perform HIV testing
- Who can consent to and receive HIV testing (e.g., teenagers or intoxicated persons)
- Provision of confidential vs. anonymous testing
- Record keeping and ensuring confidentiality
- Reporting HIV testing results
- Provision of partner elicitation and notification services
- Laboratory certifications or licensure
- Quality assurance procedures for HIV testing

Additionally, the following federal policies apply to all HIV testing programs:

## Laboratory certificate requirements

Nonclinical HIV testing sites using waived rapid HIV tests must either obtain their own certificate of waiver under CLIA (the Clinical Laboratory Improvement Amendments of 1988), or establish an agreement to work under the CLIA certificate of an existing laboratory.<sup>14,15</sup> CLIA outlines quality standards for laboratory testing—including rapid HIV testing—to ensure the accuracy, reliability, and timeliness of patient test results. More information about CLIA certification and CLIA-waived tests can be found on CDC's HIV/AIDS website (<http://www.cdc.gov/hiv/testing/nonclinical/clia.html>). Agencies should contact their state or local health department for more information, including how to apply for a CLIA waiver.

## Health information compliance

All health care providers—including HIV testing providers—must comply with federal and state laws that protect patients' health information, such as those set out in the Health Information Portability and Accountability Act of 1996 (HIPAA).<sup>16</sup> HIPAA provides clients and patients access to their medical records and gives them control over how their health information is used and disclosed. Clients and patients can give permission to share their health information with anyone, including friends, family members, and organizations that provide referral services. This means that couples who wish to be tested and receive their results together may do so under HIPAA if both partners are in agreement.

## Data security and confidentiality

All data collected by nonclinical HIV testing sites should adhere to the standards outlined in Data Security and Confidentiality Guidelines for HIV, Viral Hepatitis, Sexually Transmitted Disease, and Tuberculosis Programs.<sup>17</sup> These guidelines provide recommendations related to record keeping, data collection, data management, and data security.

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<sup>14</sup> CDC. CLIA home page. <http://www.cdc.gov/clia/>. Updated October 2014. Accessed March 24, 2016.

<sup>15</sup> CDC. Fact Sheet: CLIA certificate of waiver. <http://www.cdc.gov/hiv/testing/nonclinical/clia.html>. Updated February 2015. Accessed March 24, 2016.

<sup>16</sup> NHS. Health information privacy. <http://www.hhs.gov/hipaa/index.html>. Accessed March 24, 2016.

<sup>17</sup> CDC. Data security and confidentiality guidelines for HIV, viral hepatitis, sexually transmitted disease, and tuberculosis programs: standards to facilitate sharing and use of surveillance data for public health action. <http://www.cdc.gov/nchhstp/programintegration/docs/pcsidatasecurityguidelines.pdf>. Published 2011. Accessed March 24, 2016.

<sup>18</sup> OSHA. *Occupational Safety and Health Standards, Code of Federal Regulations*. Bloodborne Pathogens, title 29, section 1910.1030. [https://www.osha.gov/pls/oshaweb/owadisp.show\\_document?p\\_id=10051&p\\_table=STANDARDS](https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_id=10051&p_table=STANDARDS). Updated April 2012. Accessed March 24, 2016.

<sup>19</sup> Siegel JD, Rhinehart E, Jackson M, Chiarello L, and the Healthcare Infection Control Practices Advisory Committee. 2007 Guideline for isolation precautions: preventing transmission of infectious agents in healthcare settings. <http://www.cdc.gov/hicpac/pdf/isolation/Isolation2007.pdf>. Accessed March 24, 2016.

## Universal precautions for employee, volunteer and consumer safety

The Occupational Safety and Health Administration (OSHA) has established basic precautions designed to keep employees and consumers safe when they might come into contact with blood or other body fluids (e.g., saliva, urine).<sup>18,19</sup> These precautions are known as "universal precautions" and should be observed by all HIV testing providers. They include the following:

- Wash hands or other skin surfaces immediately before and after handling blood or other body fluids. If soap and water is not available, alcohol-based hand sanitizer may be used.
- Use disposable gloves (preferably latex); change gloves between clients.
- Do not eat, drink, apply makeup, or handle contact lenses in the testing area.
- Do not keep food or drink in refrigerators, containers, shelves, cabinets, or countertops where potentially infectious materials are present.
- Dispose of lancets, needles, or other fluid-touched items (e.g., gauze) in proper biohazard containers.
- Disinfect all work surfaces and items before and after testing with 10% bleach solution or Environmental Protection Agency-approved disinfectant.

In the context of HIV testing, the most likely occupational exposure will be through blood collected via fingerstick or blood draw, needlestick injuries while collecting specimens, or through sharp injuries. Other staff, such as janitorial staff who clean up the areas where testing is conducted, may also be occupationally exposed. Agencies must protect workers who may come into contact with blood or other body fluids, and make arrangements for safe and proper disposal of all HIV testing waste.

If you come into contact with body fluids, report this exposure to your supervisor immediately and seek medical guidance to initiate postexposure prophylaxis (PEP).<sup>20</sup>

## Provider safety

Agencies should establish policies and procedures to keep staff and volunteers safe in HIV testing settings. These policies may include language about the number of staff required to be onsite; service provision hours; emergency preparedness; and staff conduct in outreach sites, mobile testing units, and HIV testing events. Additional considerations for providing HIV testing in outreach settings (e.g., a bar, bathhouse, public park), including planning and implementation tools, can be found in Chapter 8 of the Program Manager Guide.

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<sup>20</sup> Kuhar DT, Henderson DK, Struble KA, et al. Updated US Public Health Service guidelines for the management of occupational exposure to human immunodeficiency virus and recommendations for postexposure prophylaxis. *Infect Control Hosp Epidemiol* 2013;34(9):875-92.

## Quality Assurance

Establishing and implementing Quality Assurance (QA) activities can help ensure that you agencies are delivering accurate test results, meeting program objectives, and delivering services according to established procedures. Each agency should develop a QA plan outlining their agency's QA activities, which might include:

- Running test kit controls according to the manufacturer's protocols
- Conducting HIV testing data reviews, including medical charts and client data forms
- Conducting role plays with peers, or between supervisors and peers
- Holding team meetings to review activities, discuss problems and concerns, and identify solutions
- Case conferencing to discuss challenging client cases and identify solutions
- Eliciting client feedback through surveys or interviews
- Conducting refresher trainings
- Performing direct observation of HIV testing sessions (with client permission)
- Receiving implementation support from CBA partners
- Reviewing client informational materials to ensure cultural appropriateness and accuracy
- Reviewing community referral and linkage resources, and establishing partnerships

QA activities are most effective when conducted on a regular basis, and when a combination of approaches is used. QA may be coordinated with local and state health department staff.

For detailed information about components of a QA program, standards of HIV testing service delivery, and establishing a QA plan for your agency, please see Chapter 9 of the Program Manager Guide.<sup>21</sup> For details about establishing QA specifically for rapid HIV testing, please see Chapter 4 of this Implementation Guide and the latest CDC guidelines on this topic.<sup>22</sup>

## Monitoring and Evaluation

Monitoring and Evaluation (M&E) activities assess the resources that go into a program (e.g., staff, funding), the services provided (e.g., tests provided, referrals provided), and the results of the program (e.g., new HIV diagnoses, successful linkage to care) to determine whether the program is meeting its objectives. Every HIV testing program should conduct M&E activities to assess and track program performance, to identify areas in need of improvement, and to ensure accountability to stakeholders. HIV testing providers play a critical role in M&E activities because they are responsible for the accuracy of client-level data and reporting.

M&E begins with establishing HIV testing program targets based on formative work, your agency's capacity for client flow, and requirements established by your funders. You might establish targets for the total number of clients tested per month, the proportion of testing clients who represent your focus population, the proportion of clients who are tested as couples, and/or the total number of new HIV diagnoses per month. Much of this work will be established in advance by your agency's program manager. See Chapter 3 for more information on targeting and recruitment of your focus population.

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<sup>21</sup> ICF Macro, Inc. Planning and implementing HIV testing and linkage programs in non-clinical settings: a guide for program managers. [https://effectiveinterventions.cdc.gov/docs/default-source/public-health-strategies-docs/HIVTestingImplementationGuide\\_Final.pdf](https://effectiveinterventions.cdc.gov/docs/default-source/public-health-strategies-docs/HIVTestingImplementationGuide_Final.pdf). Published 2012. Accessed March 24, 2016.

<sup>22</sup> CDC. Quality assurance guidelines for testing using rapid HIV antibody tests waived under the Clinical Laboratory Improvement Amendments of 1988 [http://www.cdc.gov/hiv/pdf/testing\\_qa\\_guidelines.pdf](http://www.cdc.gov/hiv/pdf/testing_qa_guidelines.pdf). Published 2007. Accessed March 24, 2016.

Once you have established targets for your program, you will need to collect data on each of your clients in order to assess whether you are meeting those targets. This includes demographics, HIV risk behavior, HIV test results, and linkage to HIV medical care. Standard data collection tools (e.g., forms, logbooks) should be used. See the “HIV Test Form” at <http://chfs.ky.gov/forms>.

Once client-level data are collected, they should be reviewed for completeness and accuracy, and stored in a secure location. These data should be compiled on a regular basis (e.g., monthly), and trends should be tracked over time. Reports should be produced and shared with stakeholders, including HIV testing program staff, board of directors, health department, and KDPH. Personally identifiable information (PII) such as client names and locating information should not be disclosed in these aggregate reports. Your HIV testing program should establish a process for reviewing these data on a regular basis to determine whether you are meeting your goals and objectives, and make adjustments in your program strategies accordingly. For example, if your monthly report illustrates that only 40% of your HIV testing clients are from your focus population, you may wish to implement new recruitment approaches the following month to increase that number to 60%. Including all stakeholders in the process of data sharing and review ensures that everyone has the same understanding of program targets and achievements, and gets everyone involved in identifying solutions for program improvement. Some agencies may wish to appoint a data monitor to be in charge of data quality and reporting, but all staff have a role in ensuring successful M&E.

HIV testing agencies funded by KDPH/CDC can find more information about testing data requirements online here, as an example of requirements associated with a particular funding announcement: <http://www.cdc.gov/hiv/funding/announcements/ps11-1113/index.html>. For questions about National HIV Prevention Monitoring and Evaluation (NHME) data requirements, contact the NHME Service Center at [NHMEservice@cdc.gov](mailto:NHMEservice@cdc.gov), or 1-855-374-7310. Documents about data system requirements and procedures for key entering and uploading NHME data for submission to CDC can be found on the EvaluationWeb help page at <http://evaluationweb.com/help/>.

Additionally, Chapter 9 of the Program Manager Guide contains information about M&E, including a sample tool for conducting a yield analysis.<sup>23</sup> There is also an accompanying evaluation guide titled Evaluation Guide for HIV Testing and Linkage Programs in Non-clinical Settings.<sup>24</sup> Both documents are available on CDC's website, and should be referenced for more detailed information.

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<sup>23</sup> ICF Macro, Inc. Planning and implementing HIV testing and linkage programs in non-clinical settings: a guide for program managers. [https://effectiveinterventions.cdc.gov/docs/default-source/public-health-strategies-docs/HIVTestingImplementationGuide\\_Final.pdf](https://effectiveinterventions.cdc.gov/docs/default-source/public-health-strategies-docs/HIVTestingImplementationGuide_Final.pdf) Published 2012. Accessed March 24, 2016.

<sup>24</sup> ICF Macro, Inc. Evaluation guide for HIV testing and linkage programs in non-clinical settings. [https://effectiveinterventions.cdc.gov/docs/default-source/public-health-strategies-docs/Final-HIV\\_Testing\\_in\\_NonClinical\\_Evaluation\\_Manual.pdf](https://effectiveinterventions.cdc.gov/docs/default-source/public-health-strategies-docs/Final-HIV_Testing_in_NonClinical_Evaluation_Manual.pdf). Published 2012. Accessed March 24, 2016.

## Chapter 3

### TARGETING AND RECRUITMENT

This chapter provides information on targeting and recruitment for HIV testing. Targeting and recruitment is the process by which persons from your focus population are located, engaged, and motivated to access HIV testing services. Regardless of whether HIV testing providers are directly involved in targeting and recruitment, they should be aware of how their HIV testing services are messaged in the community and how clients reach them for testing.

#### Defining Targeting

Targeting is the process for defining how you will direct your HIV testing services to identify persons who are unaware of their HIV status and who are at greatest risk for HIV infection. Appropriately targeting your HIV testing services to these highest-risk populations is necessary for maximizing resources, and for identifying undiagnosed HIV-positive persons in need of HIV medical care, treatment, and prevention services. Targeting can also help you identify high-risk HIV-negative persons needing important HIV prevention services, such as PrEP, nonoccupational postexposure prophylaxis (nPEP), and other social and behavioral interventions.

In nonclinical settings, it is important to target your services to identify high-risk individuals who do not access health care services or who may not otherwise have access to HIV testing in clinical settings—these are the persons who may benefit most from HIV testing services in nonclinical settings, and so these are the persons you should attempt to recruit into your program. Additionally, in defining your focus population and how to reach them, your program should consult multiple data sources, including local epidemiologic and surveillance data, recent programmatic monitoring and evaluation data, and your health department's Comprehensive HIV Prevention Jurisdictional Plan.<sup>25</sup> Members of your focus population, agency staff, and other service providers can also be important sources of information for identifying high-risk populations, where they congregate in the community, and the best ways of reaching them. Key informant interviews, which are brief interviews to obtain feedback from these groups, can be used for this purpose.

Each agency will need to define or segment their focus populations, which should include both their primary focus population and their secondary focus population (or subpopulation). In order to narrow your overall focus population to reach persons most at risk for HIV infection, you will need to know what high-risk behaviors and other factors are related to increased risk in your community, who is engaging in these behaviors or is affected by these factors, and where to identify these populations. This will help you tailor your messages and services in a way that resonate with your focus population and plan for how to reach them.

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<sup>25</sup> CDC. Comprehensive high-impact HIV prevention projects for community-based organizations: CDC-RFAPS15-1502. <http://www.cdc.gov/hiv/funding/announcements/ps15-1502/>. Published October 2014. Accessed March 24, 2016.

In many cases, your HIV testing program's focus population will be determined by your funder, state or local health department, CDC, or agency management. For an example of a proposed focus population worksheet associated with a CDC funding announcement, see [http://www.cdc.gov/hiv/pdf/AttachmentB\\_PS15-1502\\_Proposed\\_Target\\_Pop\\_Wksht\\_Final.pdf](http://www.cdc.gov/hiv/pdf/AttachmentB_PS15-1502_Proposed_Target_Pop_Wksht_Final.pdf). Agencies should involve HIV testing providers in discussions and decision-making processes about targeting; providers are often connected with the community and can be an important source of information.

Much more detail on targeting, including sources and types of data that can be useful for targeting, is provided in the Program Manager Guide.<sup>26</sup>

## Defining Recruitment

Recruitment begins once you have defined your focus population and identified where and how to reach them (i.e., targeting). Community assessment or formative evaluation can provide valuable information on recruitment, given the dynamics of different communities, and the potential for certain strategies to work better than others with high-risk groups.

Your agency should develop a recruitment plan that outlines when, where, and how recruitment of the focus population should be done. The plan should include ideas about where you will reach your focus population, as well as the specific recruitment strategies and messages that will be used for reaching them and engaging them in HIV testing. You might find that your focus population is accessible at a physical location (e.g., a particular neighborhood, bar, or weekly meeting) or in a virtual space (e.g., Internet chat group, social media).

Once you have defined the recruitment strategies you will use to engage your focus population and outlined these in your plan, you should pilot these strategies and make refinements based on your results. Even after you begin implementing your recruitment strategies, you should routinely monitor your HIV testing services to determine if you are meeting your targets, and make adjustments to your recruitment strategies as needed. For example, if you find over the course of 1 month that you have not tested anyone who is HIV-positive, you might need to revise your recruitment strategies to better reach persons with undiagnosed HIV infection or at high-risk for acquiring HIV infection.

## Recruitment Strategies

Agencies should aim to deliver strategic, culturally competent, community-based recruitment strategies that engage the focus population and motivate them to access HIV testing services. Organizations should collaborate with other organizations that have a history of working with and recruiting the focus population. They should seek input from community stakeholders, such as the Community Advisory Board, to select the most appropriate program promotion and recruitment strategies. Community stakeholders can also be useful for crafting recruitment messages, which may focus on increasing public awareness of the agency's services, destigmatizing HIV and HIV testing, and providing key information about HIV and HIV testing.

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<sup>26</sup> ICF Macro, Inc. Planning and implementing HIV testing and linkage programs in non-clinical settings: a guide for program managers. [https://effectiveinterventions.cdc.gov/docs/default-source/public-health-strategies-docs/HIVTestingImplementationGuide\\_Final.pdf](https://effectiveinterventions.cdc.gov/docs/default-source/public-health-strategies-docs/HIVTestingImplementationGuide_Final.pdf) Published 2012. Accessed March 24, 2016.

The 6 primary categories of recruitment strategies are the following:

1. Street-based and venue-based outreach
2. Internet outreach
3. Internal referrals
4. External referrals
5. Social networking
6. Social marketing

## Street-based and venue-based outreach

**Street-based** and **venue-based** outreach are done by engaging the focus population in their own environment, such as a particular street, neighborhood, hot spot, or venue (e.g., a bar, hotel, or community center). Outreach workers, who may include HIV testing providers, aim to reach the focus population with key messages about HIV and HIV testing. HIV testing services may also be offered in conjunction with street- and venue-based outreach, if appropriate, and some agencies will bring a mobile testing unit, such as a van or tent, to provide HIV testing for the focus population.

## Internet outreach

**Internet outreach** involves reaching the focus population through online venues, such as chat rooms, social networking sites, hook-up sites, and mobile applications. Agencies can promote HIV testing services including couples or partner testing through these approaches; provide information about HIV prevention, care, and treatment; or schedule appointments for clients seeking HIV testing. Internet-based outreach may be especially useful for reaching young people and MSM who do not identify as gay or who cannot be found in traditional outreach settings.

## Internet referrals

**Internet referrals** means accessing the focus population through other services offered at the HIV testing agency, such as syringe services programs, substance abuse programs, mental health services, evidence-based HIV prevention interventions, sexually transmitted disease (STD) testing and treatment programs, and HIV medical care (for partners of people already in care). This approach can be successful, but persons with high-risk behaviors may not access these services independently, so additional recruitment strategies should also be used.

## External referrals

**External referrals** means that persons from the focus population are referred to HIV testing services by agencies outside the HIV testing program. External agencies may include syringe services programs, substance abuse programs, mental health services, evidence-based HIV prevention interventions, STD testing and treatment programs, HIV medical care, and homeless shelters. These offsite programs identify high-risk clients who are accessing their services and send them to your agency for HIV testing. Building strong partnerships with external agencies that tend to serve high-risk clients is important, as is sharing information with them about how to make appropriate referrals to your program.

## Social networking

**Social Networking Strategy (SNS)** is a peer-driven approach to recruitment that involves identifying HIV-positive or high-risk HIV-negative persons from the community to serve as "recruiters" for your agency. Recruiters deliver key messages and encourage HIV testing among high-risk persons in their social, sexual, or drug-using networks. They may use coupons or invitations as a way of documenting that they have delivered these messages to potential clients. The recruiters are trained or "coached" on the best approaches to reach their peers, including who should be reached through this approach and what messages can motivate their peers to be tested for HIV. Partner referral is a type of social networking that involves recruiters referring their sexual partners to an HIV testing program. Recruiters may refer their sexual partners to be tested alone, or recruiters may accompany their partners and be tested together, as outlined in Chapter 6 on Couples HIV Testing and Counseling.

## Social marketing

**Social marketing** is the use of media (e.g., flyers and brochures, posters, print advertisements, radio and television advertisements, or Internet advertisements) to recruit clients into HIV testing programs. Organizations can develop their own social marketing campaigns but are encouraged to use existing resources, such as those available from CDC, and tailor them to their jurisdiction's specific requirements. CDC's Act Against AIDS campaign materials can be accessed at <http://www.cdc.gov/actagainstaids/> and additional materials are available at <http://effectiveinterventions.cdc.gov/>.

## Implementing Recruitment

In order to achieve the best results, your agency should employ multiple recruitment strategies to reach the focus population. You may even choose to use all 6 recruitment strategies because they each have their own benefits and potential for reaching different subgroups of the focus population. When selecting your recruitment strategy, your agency should consider staff safety, agency capacity, and availability of resources.

Recruitment of the focus population is essential to the success of your high-impact HIV testing program. In order to have an effective and innovative program, resources should be dedicated to carrying out your recruitment plan. You may have the most success if you

- hire and train specific recruitment staff who are separate from HIV testing staff
- build partnerships in the community to ensure multidirectional referrals and expand your reach
- use innovative approaches for reaching the focus population through Internet and social media
- offer incentives to reach previously unreached populations, generate interest in new services, or obtain buy-in for testing at high-risk venues (e.g., bathhouse or bar) where clients might need extra motivation to access HIV testing

## Incentives

Incentives can be resource intensive for your agency, but can also be very useful for engaging persons who are not otherwise testing, or for increasing demand for a new service, such as couples HIV testing and counseling. There are 3 primary ways in which incentives might be used:

1. Client incentives: Incentives are delivered directly to clients when they access HIV testing. Agencies might offer gift cards, food items, clothing, other goods, or sometimes even cash to motivate clients to seek HIV testing.
2. Recruiter incentives: Agencies using SNS approaches may deliver incentives to recruiters when the clients they recruit show up for HIV testing. Recruiters should be encouraged to refer clients from the focus population, and may wish to specifically focus on referring first-time testers, couples or partners, and high-risk persons in the social networks of HIV-positive clients.
3. Agency incentives: This type of motivation is also referred to as performance-based payment. Funders, such as health departments, reimburse their contractors for achieving certain targets—such as first-time testers, previously undiagnosed persons, or couples—or for confirming linkage to care after receiving an HIV-positive test result.

Challenges to using incentives include the potential to attract repeat testers who are more interested in the incentive than the HIV test, interagency competition, and sustainability. In developing an incentive plan, agencies should identify an appropriate incentive rate for reaching the focus population. It may be useful to consult with community advisory boards or clients to elicit feedback on appropriate incentives for HIV testing.

Agencies should regularly revisit and refine their recruitment strategies. If, through M&E, you discover that your testing program is not reaching the focus population or you are not on track to meet your targets, you will need to try different recruitment strategies.

More information on targeting and recruitment can be found in Chapter 3 of the Program Manager Guide.

## Chapter 4

# HIV TESTS AND TESTING STRATEGIES

## Testing Basics

Your agency should have already selected the types of test kits (SURE CHECK and OraQuick) that you will use to perform “rapid-rapid” HIV testing, and if you will be performing HIV testing, you should receive training on how to conduct these tests. This chapter includes important information you should know about the different types of HIV test kits that are available, so that you are able to answer questions that your clients might have.

As mentioned in Chapter 2, agencies are encouraged to use the best possible testing technologies and specimens that allow them to detect HIV infection as early as possible after exposure. Immediately after infection, during what is referred to as the eclipse period, no HIV test can detect infection. Following this period is the acute infection period, the interval between when HIV ribonucleic acid (RNA) can first be detected using a nucleic acid test and when antibodies can first be detected. Most antibody tests cannot detect acute HIV infection, and persons with acute HIV infection can be highly infectious.<sup>27</sup>

Every test has a window period during which the test cannot detect HIV infection. That period depends on the type of test being used, as well as the individual being tested. The window period includes the eclipse period (when no test can detect infection) up through the time when the particular test becomes reactive.

There are 3 types of HIV diagnostic tests: nucleic acid tests (NATs), antigen/antibody tests, and antibody tests.<sup>28</sup> NATs detect HIV RNA directly and have the shortest window period, followed by antigen/antibody tests, and then antibody tests.

## Nucleic acid tests

Before antibody tests are able to detect the body's response to HIV infection, NATs can detect the presence of the virus in blood. NATs can detect very early infection, as early as 10 days after infection. NATs are used for HIV testing in many laboratory settings.

Additional information is available at CDC's website for U.S. HIV tests (<http://www.cdc.gov/hiv/testing/>).

## Combination antigen/antibody tests

Combination antigen/antibody tests detect both the antibody to HIV and the antigen “p24”—a protein that is part of the virus itself. Because the p24 antigen can be detected before antibodies appear, combination tests can identify very early infections. These tests—used with blood specimens collected from the vein—are recommended by CDC as the first test in the laboratory testing algorithm.<sup>29</sup>

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<sup>27</sup> Patel P, Borkowf CB, Brooks JT, et al. Estimating per-act HIV transmission risk: a systematic review. *AIDS* 2014;28(10):1509-19.

<sup>28</sup> CDC. Fact Sheet: HIV testing in the United States. <http://www.cdc.gov/nchhstpx-test-2015/newsroom/docs/factsheets/hiv-testing-us-508.pdf> Published November 2014. Accessed March 24, 2016.

<sup>29</sup> CDC and Association of Public Health Laboratories. Laboratory testing for the diagnosis of HIV infection: updated recommendations. <http://stacks.cdc.gov/view/cdc/23447> Published June 27, 2014. Accessed March 24, 2016.

Combination antigen/antibody rapid tests can be used for point-of-care testing, but detect infection several days later than the laboratory-based combination tests.<sup>30</sup> The evidence is inconclusive about the ability of combination antigen/antibody rapid tests to accurately detect the p24 antigen on whole blood specimens, and CDC has not provided recommendations about the use of these tests.<sup>31</sup>

## Antibody tests

HIV antibody tests detect the presence of antibodies against HIV, which typically develop within 2 to 8 weeks after exposure to the virus. An antibody test can be conducted on a sample of blood or oral fluid. Many antibody tests are rapid tests, which means results can be returned on the same day, or within the same hour, or even within minutes. Rapid HIV antibody tests can be attractive for use in outreach settings because these settings may not be equipped to conduct venipuncture, and clients can get the results from their screening test quickly.

Oral fluid antibody tests have been shown to detect infection a month or more later than blood-based tests because there is a lower concentration of HIV antibodies in oral fluid than in blood.<sup>32,33,34</sup> Oral fluid is not ideal for identifying early HIV infection, but may also be appealing in outreach settings because collecting oral fluid does not involve a fingerstick or venipuncture to perform the test. No antigen/antibody or nucleic acid tests are available for use with oral fluid.

Blood-based rapid HIV antibody tests are widely available in most nonclinical HIV testing sites, and blood (whole blood, serum, or plasma) is the preferred specimen for HIV testing because tests conducted with blood are more likely to detect early infection than those conducted with oral fluid. If your organization must use oral fluid for testing, then you should inform HIV testing clients and patients of the limitations of this type of specimen for testing.

<sup>30</sup> Masciotra S, Luo W, Youngpairoj AS, et al. Performance of the Alere Determine HIV-1/2 Ag/Ab Combo Rapid Test with specimens from HIV-1 seroconverters from the US and HIV-2 infected individuals from Ivory Coast. *J Clin Virol* 2013;58(Suppl 1):e54—e58.

<sup>31</sup> Stekler JD, O'Neal JD, Lane A, et al. Relative accuracy of serum, whole blood, and oral fluid HIV tests among Seattle men who have sex with men. *J Clin Virol* 2013;58(Suppl 1):e119—e122.

<sup>32</sup> Luo W, Masciotra S, Delaney KP, et al. Comparison of HIV oral fluid and plasma antibody results during early infection in a longitudinal Nigerian cohort. *J Clin Virol* 2013;58(Suppl 1):e113—e118.

<sup>33</sup> Mortimer PP, Parry JV. Detection of antibody to HIV in saliva: a brief review. *Clin Diagn Virol* 1994;2(45):231-243.

<sup>34</sup> Curlin M, Martin M, Gvetadze R, et al. Analysis of false negative HIV tests based on oral fluid in 3 clinical trials. Presented at: 22nd Conference on Retroviruses and Opportunistic Infections; February 23-26, 2015; Seattle, WA. Abstract 635. <http://www.croiconference.org/sessions/analysis-false-negative-hiv-tests-based-oral-fluid-3-clinical-trials>. Accessed March 24, 2016.

## TESTING APPROACHES

### Laboratory-based testing for Clinical Settings

If a blood specimen is drawn in a clinical setting for the laboratory, all testing can be conducted using the initially drawn specimen. For blood specimens sent to a laboratory, CDC and the Association of Public Health Laboratories recommend the use of an antigen/antibody combination assay for the first test, and—if reactive—additional testing with a HIV1/2 differentiation assay and NAT when needed.<sup>35</sup>

Some nonclinical HIV testing sites work closely with laboratories to process the site's HIV tests and send back the test results. In this type of arrangement, your agency will collect and prepare blood or oral fluid samples from your clients and ship them to the laboratory where the HIV tests will be performed. If your testing site is conducting laboratory-based HIV testing on blood samples, you will need to follow the appropriate sample collection and preparation procedures as defined by the laboratory doing the testing. The procedure for sample collection and preparation will vary depending on the test kits and testing algorithm used by the laboratory and according to the test manufacturer's established requirements. It is very important that you follow these procedures precisely to ensure an accurate test result. Each laboratory has procedures that dictate the type and minimum size of sample collection tubes to be used, shipping requirements, temperature requirements, preparation of the samples, timeframes associated with processing the test, and reporting results.

Some laboratories and health departments may provide training on sample collection and preparation, safe packaging, and transportation.<sup>36</sup> Consult with your agency and the laboratory that will be performing HIV testing to see whether this training is available.

More information on laboratory-based HIV tests is available at <http://www.cdc.gov/hiv/testing/laboratorytests.html>.

### Point-of-care testing (Rapid testing)

Most rapid HIV testing performed in nonclinical settings is considered "point-of-care" or "point-of-contact" because the test is processed onsite where the client is receiving services. Results of rapid tests are often provided in less than 1 hour or even within minutes. The testing may be called "rapid HIV testing" or "CLIA-waived rapid HIV testing."

CLIA establishes criteria for rapid HIV tests based on 3 different levels of complexity: waived, moderate complexity, and high complexity. CLIA-waived rapid HIV antibody tests are the most common type of tests used in nonclinical HIV testing settings, although some nonclinical settings are also starting to incorporate CLIA-waived combination antigen/antibody rapid tests. CLIA-waived rapid HIV tests can be used in many different settings and are typically used in nonclinical settings because of their ease of use and fast test results. A list of CLIA-waived rapid HIV tests is available at <http://www.cdc.gov/hiv/testing/nonclinical/>.

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<sup>35</sup> CDC and Association of Public Health Laboratories. Laboratory testing for the diagnosis of HIV infection: updated recommendations. <http://stacks.cdc.gov/view/cdc/23447>. Published June 27, 2014. Accessed March 24, 2016.

<sup>36</sup> DaklaPack Medical. UN3373 Medical Packaging: Regulations. <http://www.un3373.com/info/regulations/>. Accessed March 24, 2016.

Instructions for specimen collection, preparation, and performance of rapid HIV tests are provided by the manufacturer in the test kits. Additionally, many public health laboratories have job aids that can be adapted and used by HIV testing providers. You should always follow the manufacturer's instructions and have them available in the testing area for easy reference. If there are any questions about the test kits or how to perform the test, you should call the manufacturer's customer service number, which is provided on the product insert.

All HIV testing providers should be trained in how to perform rapid HIV tests, including the specimen collection approach that is used at their testing site (i.e., venipuncture, fingerstick, or oral fluid). Many health departments offer this training, and CDC also has a Rapid HIV Testing Online Course that provides some information on how to conduct various types of rapid HIV tests. Instructions for accessing CDC's online course are available at <http://effectiveinterventions.cdc.gov/en/HighImpactPrevention/PublicHealthStrategies/CTR.aspx>.

## Home tests

Home HIV testing is an emerging area of interest among consumers and HIV testing providers because it can be an effective method for reaching people who are not otherwise getting tested. This approach may also be helpful in reaching couples and persons in sexual relationships.<sup>37</sup> Some nonclinical HIV testing sites are finding opportunities to engage with home testing clients by being available for follow-up counseling or by actually distributing the tests and serving as a resource for clients who have completed testing and interpreted their results. Strategies for engaging persons who test positive with a self-test should be explored so they can be linked to medical care quickly.

As of November 2015, there are currently 2 home HIV tests available on the market: the Home Access HIV-1 Test System (where a self-collected sample is mailed to a lab for testing) and the OraQuick In-home HIV test. These tests can be found for purchase online and in stores. Consumers should ensure that any HIV test advertised for home use is FDA approved before purchasing.

More information on home testing is available at <http://www.cdc.gov/hiv/testing/hometests.html>.

## TESTING ALGORITHMS

Most HIV testing conducted in nonclinical settings will include an initial HIV test and, if the initial HIV test is reactive, a follow-up HIV test. If follow-up testing is required, both the initial and follow-up tests are considered part of the same testing event for reporting purposes for CDC-funded programs.

**An initial HIV test** will either be an antibody test or combination antigen/antibody test. It may involve sending blood or oral fluid to a laboratory or obtaining blood or oral fluid for a rapid test.

**Follow-up testing** (sometimes referred to as "supplemental testing" or "confirmatory testing") is performed if the initial test result is positive. HIV tests are generally very accurate, but follow-up testing is important to be sure of the diagnosis of HIV infection.

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<sup>37</sup> Mitchell JW, Sullivan PS. HIV-negative partnered men's attitudes toward using an in-home rapid HIV test and associated factors among a sample of US HIV-negative and HIV-discordant male couples. *Sex Transm Dis* 2015;42(3):123-128.

## Laboratory testing algorithm

In 2014, CDC published new recommendations for the HIV testing algorithm in laboratory settings (<http://www.cdc.gov/hiv/pdf/HIVtestingAlgorithmRecommendation-Final.pdf>). The updated recommendations outline a new testing algorithm that begins with a combination antigen/antibody test that detects both HIV-1 and HIV-2 antibodies. This algorithm has many advantages over previous ones:

- follow-up testing does not rely on the Western blot, which does not detect early infections
- accurate diagnosis of HIV-2
- potential for earlier diagnosis of HIV-1

Note: The recommended HIV testing algorithm cannot be used with oral fluid specimens.

Some laboratories still allow submission of oral fluid specimens, but these specimens are not part of CDC's recommended algorithm. Testing oral fluid in the lab requires a different testing algorithm that includes the Western blot, which does not detect infection as early as the more sensitive blood tests recommended in the new algorithm.

## Point-of-care (rapid) testing algorithm

Unlike laboratory testing, CDC has no published guidelines for point-of-care testing algorithms. However, there are several sources of information that highlight possibilities for point-of-care algorithms.<sup>38,39,40</sup>

Point-of-care rapid HIV testing may follow 1 of 3 testing algorithms. This guideline is primarily concerned with the 3<sup>rd</sup> algorithm (rapid-rapid testing). The benefits and drawbacks of each algorithm are addressed in the Program Manager Guide and separately in a 2009 report from the Association of Public Health Laboratories and CDC.<sup>41</sup> The 3 algorithms that are common to nonclinical HIV testing settings are:

1. Single rapid test with immediate linkage to clinical provider if initial test is reactive; if initial test is nonreactive, client is presumed to be HIV-negative.
2. Single rapid test followed by laboratory-based follow-up testing if initial test is reactive; if initial test is nonreactive, client is presumed to be HIV-negative.
3. ***Single rapid test immediately followed by a second rapid test on-site if initial test is reactive.***
  - a. ***If initial test is nonreactive, client is HIV-negative.***
  - b. ***If both tests are reactive, provide immediate linkage to HIV care.***
  - c. ***If second test is nonreactive but first test is reactive, refer to laboratory or clinical provider for follow-up testing.***

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<sup>38</sup> Bennett B, Branson B, Delaney K, et al. HIV testing algorithms• a status report. <http://www.aphl.org/aphlprograms/infectious/hiv/Pages/HIV-Diagnostic-Testing-Algorithm.aspx>. Published April 2009. Accessed March 24, 2016.

<sup>39</sup> CLSI. *Criteria for Laboratory Testing and Diagnosis of Human Immunodeficiency Virus Infection; Approved Guideline*. CLSI document M53-A. Wayne, PA: Clinical and Laboratory Standards Institute; 2011.

<sup>40</sup> CDC and Association of Public Health Laboratories. Laboratory testing for the diagnosis of HIV infection: updated recommendations. <http://stacks.cdc.gov/view/cdc/23447>. Published June 27, 2014. Accessed March 24, 2016.

<sup>41</sup> Bennett B, Branson B, Delaney K, et al. HIV testing algorithms: a status report. <http://www.aphl.org/aphlprograms/infectious/hiv/Pages/HIV-Diagnostic-Testing-Algorithm.aspx>. Published April 2009. Accessed March 24, 2016.

Agencies should use the algorithm mandated by their local health department. If there are options, agencies should choose an algorithm that allows them to detect HIV as early as possible after exposure. Agencies should also consider other factors, such as feasibility of implementation, likelihood of being able to follow-up with the client, and cost.

## Specimen Collection and Preparation

Regardless of the HIV testing method you are using, you should perform specimen collection and preparation correctly and consistently to ensure the accuracy of your clients' test results. All HIV testing providers should be trained in the specimen collection procedure that is used at their agency—whether venipuncture, fingerstick, or oral fluid. Practical hands-on training should be available through your local health department. CDC's Rapid HIV Testing Online Course also provides some of this information, and can be accessed at <http://effectiveinterventions.cdc.gov/en/HighImpactPrevention/PublicHealthStrategies/CTR.aspx>.

Every test kit also has a product insert, which should be readily available to all persons conducting the HIV test. This insert should be consulted to ensure accurate procedures. However, although job aids such as the test kit insert are helpful, they should not be relied on as the sole source of information for conducting tests. All agencies should have HIV testing policies and procedures that describe instructions for accurate specimen collection and preparation, as well as safety precautions and a biohazard disposal protocol to protect clients and testing personnel. For more information, see "Universal precautions for employee and consumer safety" in Chapter 2.

## Interpreting Results

In order to deliver an accurate message about the meaning of HIV test results, you should be familiar with the testing algorithm used by your agency. Remember to use simple and clear language to explain test results to clients. We provide examples of this language for each type of result below.

### CLIA-waived rapid HIV testing

**Reactive Initial Results:** If the initial rapid HIV test (SURE CHECK) is reactive, this indicates that HIV antibodies have been detected. The result is interpreted as a preliminary positive test result and follow-up testing is required to corroborate the diagnosis. In most cases, clients who are reactive on their initial rapid HIV test are true positives; that is, they are likely to be reactive on a follow-up test (OraQuick) as well and should be prepared to receive a second positive result. For this reason, it is beneficial to immediately link clients who have two preliminary positive test results to HIV medical care and to PS. It is also important to counsel clients and to assist them with risk-reduction strategies while they wait for their follow-up health care visits.

Follow-up testing with OraQuick should be provided immediately after the client has had a reactive SURE CHECK test. Conduct a second rapid HIV test onsite, deliver the corroborative result, and link the client with HIV medical care or other services, as appropriate.

*You might say to clients: "The test result was reactive, which means it is very likely that you have HIV. We need to do a second test to make sure of the results."*

Once you have the results of the follow-up test (whether received from a laboratory or from your second rapid HIV test conducted onsite), you should deliver these as confirmed results. In most cases the results of the follow-up test will match the results of the initial test; that is, they will also be reactive and you will confirm the client's HIV-positive status.

*You might say to clients: "The results of your follow-up test were also reactive, which means you have HIV. I'd like to link you with a medical provider who will do some additional testing and get you enrolled in medical care."*

In rare cases, an initial rapid HIV test will be reactive and a follow-up test will be nonreactive. If this happens when follow-up testing is done at a clinical provider or laboratory, it will either be resolved before your agency receives the follow-up test results, or your agency should receive guidance about how to deliver these results and the next steps. However, if this happens when you are conducting a second rapid HIV test onsite, you may need to incorporate language about what this means and what the next steps are.

*You might say to clients: "The first test was reactive, and we ran a second test, which was nonreactive. Since those 2 tests gave us different results, we can't be sure about your HIV status. We are sending the blood we drew to an offsite lab for confirmation. We'll make an appointment for you to come back and get those results in 1 week."* <sup>42</sup>

**Nonreactive Results:** If the result of a rapid test is nonreactive, the test result is interpreted as HIV-negative. Depending on the window period associated with the test that you are using, clients that report recent known or possible exposure to HIV can be advised that, because of their recent exposure, it is possible the test did not detect HIV antibodies at this time. You should recommend retesting at an appropriate interval based on the client's risk and the type of test used. Chapter 5 elaborates on retesting recommendations.

*You might say to clients: "The test result does not show signs of HIV infection. However, since you mentioned that you've recently had sex without a condom with someone whose HIV status you don't know, I'd like to recommend that you get retested in \_\_\_\_ weeks."*

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<sup>42</sup> Adapted from *Oraquick-Blood StatPak Counseling Messages* developed by City and County of San Francisco Department of Public Health, Community Health Equity and Promotion Branch, Population Health Division. <http://www.sfhiv.org/wp-content/uploads/2tests-Oraquickblood-StatPakcounselingmessages02-2010.pdf>. Updated February 2010. Accessed March 24, 2016.

**Invalid Results:** If a rapid test produces an invalid result, it cannot be interpreted. Invalid results are often the result of user error, which means you may have conducted the test incorrectly. You should repeat the HIV test on a new sample obtained from the client, and may wish to call in a supervisor or other experienced HIV testing provider to assist with the test. For additional information on invalid rapid test results, refer to the package insert provided with the test kit by the manufacturer.

## Cautions regarding the window period and acute infection

In an attempt to address the window period, many agencies recommend that HIV-negative clients return for retesting 3 months after a potential exposure to HIV in order to feel more confident with their results. However, if this message is given to all clients regardless of their specific risk, this message can be diluted and clients may not fully understand the importance of identifying acute HIV infection. Furthermore, many clients may interpret this message as "3 months from their last HIV negative test," prolonging the time until they are retested and potentially missing opportunities for identifying acute infection.

If someone has acute HIV infection, they can be highly infectious and may be likely to transmit the virus to others. Clients should understand the importance of identifying HIV infection as early as possible. If a client is concerned about a recent exposure or they report symptoms of acute HIV infection such as persistent fever, swollen throat or lymph nodes, or other severe flu-like symptoms, they should be referred immediately to their doctor or other local clinic for acute infection testing. You should emphasize the need for using protection until acute infection can be ruled out. If testing immediately for acute infection is not an option, then the client should be tested at your site and then retested 3 months after their potential exposure.

## False-negative test results

False-negative test results occur when someone who is infected with HIV receives an HIV-negative test result. This scenario has been documented in persons on ART<sup>43</sup> and in some persons receiving PrEP.<sup>44</sup> However, additional data are needed to determine the extent to which test performance is affected by these factors. HIV testing providers may wish to ask clients if they are currently using ART, nPEP/PEP, or PrEP, in order to determine if additional testing is necessary to rule out a false negative result. False-negative results may occur for other reasons as well, such as test design, improper test procedures, or mislabeling of the specimen.

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<sup>43</sup> O'Connell RJ, Merritt TM, Malia JA, et al. Performance of the OraQuick rapid antibody test for diagnosis of human immunodeficiency virus type 1 infection in patients with various levels of exposure to highly active antiretroviral therapy. *J Clin Microbiol* 2003;41(5):2153-2155.

<sup>44</sup> Curlin M, Martin M, Gvetadze R, et al. Analysis of false negative HIV tests based on oral fluid in 3 clinical trials. Presented at: 22nd Conference on Retroviruses and Opportunistic Infections; February 23-26, 2015; Seattle, WA. Abstract 635. <http://www.croiconference.org/sessions/analysis-false-negative-hiv-tests-based-oral-fluid-3-clinical-trials> Accessed March 24, 2016.

## False-positive test results

False-positive test results occur when someone who is not infected with HIV receives an HIV-positive test result. This scenario is not frequent, but can occur in clients who are participating in HIV vaccine trials. HIV vaccine-induced antibodies can cause a rapid HIV antibody test to give a positive result, even though the person does not have HIV. All clients who receive an HIV-positive test result and who are also HIV vaccine trial participants should contact the vaccine trial site for evaluation or to receive a referral to HIV medical care for further evaluation and/or testing.<sup>45</sup>

False-positive test results also occur in people who have not received the HIV vaccine in the study trial. The number of clients who received false positive test results will vary based on the type of tests you use and the HIV prevalence in your setting.

False-positive results may also occur for other reasons such as those mentioned under false-negative results.

## Delivering test results

Your agency should have clearly defined protocols for delivery of HIV test results. These protocols can be described in your agency's HIV testing policies and procedures. The KDPH's "Core Clinical Services Guide" requires results to be delivered in person. It is most important that clients do receive their results, as well as referrals to and linkage with appropriate follow-up services.

## Face-to-face delivery

Delivering results face-to-face allows you to have some engagement with the client, to assess their reaction to their test results, and to link them with HIV medical care or prevention services, if indicated, or to other appropriate follow-up services. For most nonclinical sites conducting rapid HIV testing, results can be delivered face-to-face during the same visit at which the client was tested. Per KDPH, it is required that HIV results be delivered face-to-face.

## Telephone or Internet delivery

KDPH's "Core Clinical Services Guide" prohibits giving results over the phone and requires that results are given face-to-face. See <http://chfs.ky.gov/dph/CCSG2015.htm>.

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<sup>45</sup> Cooper CJ, Metch B, Dragavon J, et al. Vaccine-induced HIV seropositivity/reactivity in noninfected HIV vaccine recipients. *JAW* 2010;304(3):275-283.

## Written results

Clients sometimes request written copies of their test results. If you are delivering written HIV-negative test results, the results should be accompanied by a clear statement about the meaning of the test results, relative to the window period of the test used. It may also be useful to indicate when the client should return for retesting. If your agency is providing written test results they should be provided on your agency letterhead or a similar form and should clearly state the following:

- The name of your agency and the date the test was conducted
- The test result (positive or negative)
- Explanation of the result relative to the window period and/or date for retesting

Written results should not be provided when conducting anonymous HIV testing. It is important to address provision of written test results in your agency's policies and procedures.

## Quality Assurance of HIV Testing

To ensure the accuracy of HIV test results, it is important that tests be performed correctly and consistently in accordance with written procedures and the manufacturer's protocols. Agencies should have HIV testing procedures that describe the following:

- Safety precautions to protect clients and testing personnel.
- Quality control (QC) procedures, including frequency of running external quality controls, documentation of QC results, and protocols for follow-up testing for clients with initial HIV-positive results.
- Materials and equipment required to support specimen collection, test performance, and documentation of test results.
- Specific steps required to perform the test correctly, as outlined in the product insert. There can be no deviations from what is in the product insert, or results may be invalid.
- Issues that may affect the accuracy of test results. These are listed in the product insert.
- Plans for addressing QC results that are not within acceptable limits. If there are issues that cannot be addressed, call the manufacturer's customer service line.

## Chapter 5

### CONDUCTING HIV TESTS WITH INDIVIDUALS

All HIV testing sessions in nonclinical settings will generally follow the same overall structure, regardless of where they are being conducted or who is being tested. That is, you will conduct certain steps before delivering the results (called "preresults steps"), and certain steps after delivering results (called "postresults steps"). This chapter will review these steps, outline essential tasks for each step, and present additional considerations for your HIV testing session with individual clients.

#### Reduced Counseling Approach

For individual HIV testing, CDC no longer supports extensive pretest and posttest counseling. Instead, HIV testing providers should conduct brief, information-based sessions tailored to their clients, as outlined below. CDC has found this strategy to be more effective in a rapid HIV testing environment.<sup>46</sup> The most widely recommended intervention pairing HIV prevention counseling and HIV testing, Project RESPECT, was originally conceived as involving traditional HIV tests that required clients to return for their test results several days after testing. Because of the changed HIV testing environment, CDC no longer supports the RESPECT intervention or the HIV prevention counseling protocol that is based on the RESPECT model.<sup>47</sup>

For couples that are tested together for HIV, the "Testing Together" protocol does include brief counseling in order to establish rapport with the couple as a unit and enhance their ability to communicate about their joint HIV risk concerns. However, this approach can also be done rapidly and follows the same "preresults steps" and "postresults steps" formats, which are described in the next chapter (Chapter 6, Conducting HIV Tests with Couples).

#### Steps for Conducting Rapid-Rapid HIV Tests with Individuals

The scenario below is for sites using two brands of 15– 20 minute rapid tests (SURE CHECK, followed up with OraQuick).

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<sup>46</sup> Metsch LR, Feaster DJ, Gooden L, et al. Effect of risk-reduction counseling with rapid HIV testing on risk of acquiring sexually transmitted infections: the AWARE randomized clinical trial. *JAW* 2013;310(16):1701-10.

<sup>47</sup> <https://effectiveinterventions.cdc.gov/en/HighImpactPrevention/Interventions/RESPECT.aspx> Accessed March 24, 2016

## SCENARIO FOR CONDUCTING AN INDIVIDUAL RAPID-RAPID HIV TEST

Rapid HIV testing ( <i>SURE CHECK</i> ) (15 minute read time)	
<b>Preresults steps</b>	
Step 1: Introduce and orient client to session	
Step 2: Prepare for and conduct initial rapid HIV test (SURE CHECK, 15 minute read time)	
Step 3: Conduct brief risk screening	
<b>Postresults steps</b>	
Step 4: Provide results of initial rapid HIV test (SURE CHECK) and if positive follow the protocol for conducting follow-up testing with OraQuick (20 minute read time)	
Step 5: Develop care, treatment, and prevention plan based on results	
Step 6: Refer and link with medical care, social and behavioral services	

In this rapid-rapid testing scenario, the HIV test is conducted as step 2 and then while the test is developing you will conduct brief risk screening.

### Second rapid HIV test provided onsite

If your agency conducts a second rapid HIV test onsite (OraQuick), you can perform this test immediately following delivery of the initial (SURE CHECK) reactive HIV test result in step 4. Although you will wait until you have the results of the second test to inform your discussions in steps 5 and 6, since most initial reactive HIV tests will prove to be true positives, you might wish to start engaging the client in some discussion about HIV care, treatment, and prevention while you wait for the results of the follow-up test.

If the second test (OraQuick) is negative, but the first test (SURE CHECK) was positive, refer the client to a health department for laboratory follow-up testing (the health department will draw blood and send it to the state lab).

We will review steps 1 through 6 for the rapid HIV testing scenario below. A job aid outlining these steps and the specific tasks to be conducted at each step is included as part of this implementation guidance package in the Appendixes, along with scripts with suggested language for each of these steps.

## Prerresults Steps

There are 3 prerresults steps for individual HIV testing:

Step 1: Introduce and orient the client to the session

Step 2: Prepare for and conduct the rapid HIV test (SURE CHECK)

Step 3: Conduct brief risk screening

### Step 1: Introduce and orient the client to the session

The first thing you will do when conducting an individual HIV testing session is introduce yourself and orient the client to the session. The key tasks for step 1 are:

- ☐ Introduce yourself and describe your role
- ☐ Provide a brief session overview, including:
  - How long the session will take
  - Process for conducting the test
  - How results are returned (i.e., at this visit)
- ☐ Obtain concurrence to proceed with the session

This step is important for building rapport and establishing client expectations for what will happen during the HIV testing session. Generally this step will take about 1-2 minutes.

### Step 2: Prepare for and conduct rapid HIV test

In step 2, you will provide the client with basic information about the HIV test. Use simple, clear language that the client can understand. Provide information in a language and at a reading level appropriate to the client. Information can be presented verbally, written, or through videos, computers, or other electronic technology. It should take approximately 1-2 minutes to provide the client with this basic information and answer any questions he or she might have about the rapid testing process. Then you will collect the sample and conduct the rapid HIV test. The key tasks for step 2 are:

- ☐ Explain the process of conducting the HIV test, including:
  - Type of test used (rapid antibody test using a fingerstick)
  - Sample collected (fingerstick blood)
  - Time until test results are ready (15 minutes for SURE CHECK)
- ☐ Explain the meaning of HIV-negative and HIV-positive test results, including:
  - Need for retesting if HIV-negative
  - Need for and process of conducting follow-up testing onsite if HIV-positive
  - Possibility of invalid result
- ☐ Obtain consent to test (oral or written)
- ☐ Distribute test kit information booklet (required for CLIA-waived tests)
- ☐ Collect specimen and conduct rapid HIV test.

You may conduct the test in the same room where the entire session is taking place, or you may take the client to an onsite laboratory where all testing is performed. If you conduct the test in the same room where the session occurs, it may be useful to set the test kits to the side while they are developing, or set up a screen to block the client's view so that the client does not get distracted or anxious watching the test develop. If the test is conducted in an onsite laboratory—or, in the case of mobile or outreach testing, in a central location where one person is responsible for doing multiple tests—you must ensure client confidentiality and accuracy of test results. Tests should always be performed according to the directions outlined in the test kit insert, and test kits should be clearly labeled to ensure that the correct results are given to the correct client.

### Step 3: Conduct brief risk screening

While you are waiting for the test results, take a few moments to conduct brief risk screening to better understand the client's HIV risk. You may use your agency's data collection tools to guide the risk screening, or you may engage the client in a brief discussion of their immediate risk concerns. You may start by asking the client how they decided to be tested, and then listening and probing for additional information about immediate, recent, or ongoing risk. If the client needs to be referred immediately for other services such as nPEP, acute infection testing, or medical care, make linkages with those services at this point. Use the information clients tell you to prepare them for their possible results, and tailor recommendations after you deliver their results.

The timing of step 3 will vary greatly depending on the HIV risk concerns of the client. This step should be conducted in 5-10 minutes. The key tasks for step 3 are:

- ☐ Ask how the client decided to be tested; listen and probe for previous testing history and indicators of increased risk including:
  - Potential exposure in last 24-72 hours (*to indicate need for nPEP*)<sup>48,49</sup>
  - Potential exposure in last 3 months (*to indicate need for acute infection testing*)
  - Symptoms (*to indicate need for acute infection testing and accessing medical care*)
  - Ongoing risk behavior or key population (MSM, PWID, partner with unknown or known HIV-positive status, transgender woman)
- ☐ Address indicators of increased risk and make immediate referrals to other services (i.e. nPEP, acute infection testing, or medical care) as indicated
- ☐ Assess the client's knowledge of HIV transmission, provide accurate information as needed
- ☐ Prepare for possible test results

<sup>48</sup> CDC. Antiretroviral postexposure prophylaxis after sexual, injection-drug use, or other nonoccupational exposure to HIV in the United States. *MMWR* 2005;54(RR-2):1-20. <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5402a1.htm>. Accessed March 24, 2016.

<sup>49</sup> NHS. Post-exposure prophylaxis. <https://www.aids.gov/hiv-aids-basics/prevention/reduce-your-risk/post-exposure-prophylaxis/>. Updated March 2015. Accessed March 24, 2016.

As you conduct the brief risk screening, your client may have questions about acute infection, the window period, and retesting for HIV, which can also be addressed while you are waiting for the test results.

### Testing frequency

CDC recommends that all adolescents and adults get tested at least once for HIV as a routine part of medical care, and that MSM and others at high risk for HIV infection be tested at least annually.<sup>50</sup> In addition, MSM and other high risk individuals might benefit from more frequent screening, such as every 3 to 6 months.<sup>51</sup>

## Postresults Steps

The 3 postresults steps for individual HIV testing are:

Step 4: Deliver results

Step 5: Develop a care, treatment, and prevention plan based on results

Step 6: Refer and link with medical care, social and behavioral services

If you are conducting laboratory testing, remember that you will include 1 additional step before delivering results. When the client returns to your site for his or her result (ideally no more than 1 week after the initial visit), you should first take a moment to check in with the client to address any HIV risk concerns or issues since the last visit. Then proceed with delivering results.

## Step 4: Delivering Results

Step 4 is the delivery of results.

If you are conducting a CLIA-waived rapid HIV test, after following the manufacturer's instructions and allowing for the appropriate time for the test to process, you will read the test device and interpret the result. If the test was conducted by another staff at your agency or outside the room where the client is waiting, obtain the result and return to the client. If the client was in the waiting room, call him or her back to the HIV testing room to receive their result. If the test result is preliminary and must be confirmed with a follow-up test, you will indicate this to the client and follow your agency's procedures (as outlined above) for follow-up testing.

The 2 key steps for delivering results are:

- ☐ Confirm the client's readiness to receive their result
- ☐ Provide a clear explanation of the client's result

Most clients will confirm that they are ready to receive their result because they came to you specifically for this purpose. Their confirmation is also an indication that you have done a successful job preparing them to receive their result during the preresults steps.

<sup>50</sup> CDC. Fact Sheet: HIV testing in the United States. <http://www.cdc.gov/nchhstp/newsroom/docs/factsheets/hiv-testing-us-508.pdf>. Published November 2014. Accessed March 24, 2016.

<sup>51</sup> CDC. HIV testing among men who have sex with men-21 cities, United States, 2008. *MMWR* 2011;60(21):694699. <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6021a3.htm>. Accessed March 24, 2016.

On very rare occasions, clients may change their mind about receiving their result. If clients state that they are not ready to hear their result, engage them in a discussion about reasons they do not feel ready. Provide motivation and support for clients by reminding them of the importance of knowing their status and making decisions for their health based on their status. Once the client has a chance to talk about his or her concerns, they may be ready to hear their result. If the client still refuses, respect his or her decision, discuss options for getting the result at a later date, and make arrangements to follow-up with the client.

## Step 5: Develop a care, treatment, and prevention plan based on results

Step 5 is to develop a care, treatment, and prevention plan with the client based on their HIV test results and risk issues identified during the brief risk screening. After receiving their test result, whether HIV-negative or HIV-positive, clients may have a hard time absorbing lots of information so it may be most effective to identify key referral services, make linkages with those services, and schedule follow-up visits if the client has additional concerns. Alternatively, another provider, such as a linkage coordinator or patient navigator, can also address the client's concerns during follow-up visits.

The overall flow of step 5 should be similar for clients who receive an HIV-negative or HIV-positive test result, but the specific tasks will be different based on their result. The tasks will also vary slightly depending on your agency's process for conducting follow-up testing for clients with an initial reactive rapid HIV test.

## HIV-NEGATIVE CLIENTS

For clients testing *HIV-negative*, the specific tasks for step 5 are:

- ☐ Explore client's reaction to result
- ☐ Discuss need for retesting based on window period of test used and client's risk
- ☐ Emphasize key risk reduction strategies that will help the client remain HIV-negative:
  - Choose less risky sexual behaviors
  - Get tested for HIV together with partner(s)
  - Use condoms consistently and correctly
  - Reduce number of sex partners
  - Talk to doctor about PrEP (as indicated, according to PrEP screening indicators)
  - Talk to doctor about nPEP (as indicated, within 3 days following a specific exposure to HIV)
  - Get tested and treated for other STDs and encourage partners to do the same
  - If partner is HIV-positive, encourage partner to get and stay on treatment
- ☐ Provide condoms

Clients receiving an HIV-negative test result may experience a range of emotions, including relief, shock, joy, or dismay. HIV testing providers should be prepared for any number of responses from clients and should remain neutral as they explore the client's reaction.

It is important to reinforce HIV prevention messages, to motivate the client to remain HIV-negative, and support them to access medical, social, and behavioral referral services, as indicated based on their risk and specific situation.

## Indications for PrEP

As the first point of contact for many high-risk HIV negative clients, HIV testing providers in nonclinical settings should not only educate clients about PrEP, but they should also know and assess for PrEP indications and refer persons at substantial risk for acquiring HIV to a PrEP counselor or medical provider where PrEP is available. PrEP providers will conduct additional risk behavior assessments or use a risk index to determine if clients are appropriate for PrEP. The tools for assessing risk behavior and the risk index can be found in the 2014 PrEP Clinical Practice Guideline<sup>52</sup> and Clinical Providers' Supplement.<sup>53</sup>

The criteria that HIV testing providers use to determine whether HIV-negative clients are at substantial risk of acquiring HIV and should be offered PrEP may be assessed over the course of the client's HIV testing session or at the end of the session after you have delivered their results. This is considered an important part of revisiting the risk discussion and reinforcing decisions that will help the client remain HIV-negative. PrEP is currently indicated for MSM at substantial risk of HIV acquisition, as well as heterosexual men and women and PWID at substantial risk of HIV acquisition. This may include persons who have unprotected sex or inject drugs with multiple partners of unknown HIV status, or persons who are in known HIV-discordant relationships, where one partner is HIV-negative and the other partner is HIV-positive.

## HIV-POSITIVE CLIENTS

For clients testing *HIV-positive*, the specific tasks for step 5 are:

- ☐ Explore client's reaction to result
- ☐ Advise on next steps for follow-up testing and provide 2<sup>nd</sup> rapid HIV test—OraQuick
- ☐ Discuss disclosure and inform about processes for partner services
- ☐ Advise to access care and treatment for HIV
  - Treatment can help people with HIV live long, healthy lives and prevent transmission
  - Other health issues can be addressed
- ☐ Emphasize key risk reduction strategies that will prevent transmission
  - Choose less risky sexual and drug-using behaviors
  - Get tested together with their partners
  - Use condoms consistently and correctly
  - Reduce number of sex partners
  - Encourage partners to be tested
- ☐ Provide condoms

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<sup>52</sup> United States Public Health Service and CDC. Preexposure prophylaxis for the prevention of HIV infection-2014: a clinical practice guideline. <http://stacks.cdc.gov/view/cdc/23109>. Accessed March 24, 2016.

<sup>53</sup> United States Public Health Service and CDC. Preexposure prophylaxis for the prevention of HIV infection-2014: clinical providers' supplement. <http://www.cdc.gov/hiv/pdf/preprovidersupplement2014.pdf>. Accessed March 24, 2016.

Clients receiving an HIV-positive result for the first time might also experience a wide range of emotions, including shock, grief, or other strong feelings. While exploring the client's reaction to his or her result, you can effectively use silence to express empathy and give the client space to absorb this new information. Attend to the client's immediate needs before moving on with the other tasks.

Advise the client on their next steps for follow-up testing to confirm the HIV-positive test result. Follow-up testing can be addressed in a number of ways:

1. Immediately link clients to medical care for follow-up testing after the initial reactive rapid test result.
2. Collect a specimen to send to a lab for follow-up testing after the initial reactive rapid test result; discuss the importance of returning to the agency to get the test result; and schedule a day and time for the client to return to the agency to get the result of the follow-up test.
3. Collect a specimen and run a second rapid test using a different rapid test to confirm the result (see Chapter 4 for additional information, including suggested language for what to do if the second test is also reactive, which is to proceed with steps 5 and 6, versus a nonreactive result, which is to refer the client to a clinical provider or collect a sample to send to the laboratory).

Although it might be difficult in this moment for clients to grasp everything you are telling them, it is important to discuss disclosure to sex partners, inform them about the processes for partner services and to reinforce the importance of accessing care and treatment. All positive clients are to be referred to and be enrolled in HIV medical care, so that they can begin accessing treatment as soon as possible to prevent transmission and help them stay healthy.

Remember that this is not the last encounter clients will have with the health care system, your primary goal should be to link clients with medical care and other necessary follow-up services—either directly or through a patient navigator or linkage counselor—as discussed in the next step.

## PARTNER SERVICES

PS is implemented with all persons who test HIV-positive. The primary function of PS is to notify the sex and drug-injecting partners of HIV-positive individuals about their potential exposure to HIV. It is a voluntary service that involves interviewing newly diagnosed HIV-positive persons to elicit names of their previous sex and drug-injecting partners who might have been exposed to HIV, then confidentially notifying these persons of their potential exposure and offering them HIV testing and linkage to HIV medical care, social, and behavioral services. Local health departments play a key role in implementing PS, and nonclinical HIV testing providers should be aware of the PS protocol followed by their agency.

Examples of partner services protocols include:

1. **Refer to local health department**—persons newly diagnosed with HIV are referred to the local health department where a Disease Intervention Specialist (DIS) conducts an interview to elicit the names and locating information of previous partners who may have been exposed to HIV. The DIS then contacts these partners and offers them HIV testing. In some jurisdictions, the health department initiates PS automatically when it receives an HIV case report form. Clients should be informed that the health department will contact them to discuss PS.
2. **DIS onsite**—some agencies have health department DIS staff onsite to interview clients who test HIV-positive.
3. **DIS on call**—some agencies work with the local health department to have DIS staff on call. When an individual is newly diagnosed with HIV, the DIS can be contacted and can arrive quickly at the agency to interview the client.

Additional information about PS can be found in the latest recommendations for PS programs.<sup>54</sup>

## Step 6: Refer and link with medical care, social, and behavioral service

Throughout the HIV testing session, you will receive information from clients that will help you determine what additional services they need in order to stay healthy, safe, and prevent HIV transmission or acquisition. Before you close the session, you will identify the necessary medical, social, and behavioral services that are appropriate for the client, and then provide the client with referrals and link them to these services. Some of these services may be provided by your agency; for others, you will need to refer outside your agency.

The 3 tasks for step 6 are:

- ☐ Identify necessary medical, social, and behavioral referral services
- ☐ Make referrals as indicated
- ☐ Track linkage to HIV medical care

For clients who test HIV-negative, some of the services you might refer them to include:

- nPEP
- PrEP
- Partner or couples HIV testing
- Retesting for HIV
- Screening and treatment for STDs, hepatitis, and/or TB
- High-impact behavioral interventions that can reduce their risk of acquiring HIV
- Reproductive health services
- Counseling and services for mental health, substance abuse, and/or domestic violence
- Insurance navigation and enrollment
- Housing
- Other social and behavioral services

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<sup>54</sup> CDC. Recommendations for partner services programs for HIV infection, syphilis, gonorrhea, and chlamydial infection. *MMWR* 2008;57(RR-9):1-83. <http://www.cdc.gov/mmwr/PDF/rr/rr5709.pdf>. Accessed March 24, 2016.

For clients who test HIV-positive, some of the services you might refer them to include:

- HIV care and treatment
- Partner services
- Medication adherence services
- Partner or couples HIV testing
- Screening and treatment for STDs, hepatitis, and/or TB
- High-impact behavioral interventions for newly diagnosed HIV-positive persons
- Reproductive health services
- Counseling and services for mental health, substance abuse and/or domestic violence
- Insurance navigation and enrollment
- Housing
- Other social and behavioral services

Chapter 7 provides more information on steps for ensuring successful referral and linkage to these services.

## Chapter 6

### CONDUCTING HIV TESTS WITH COUPLES AND PARTNERS

Couples HIV testing and counseling (CHTC), or *Testing Together*, is a relatively new approach to HIV testing, whereby 2 or more persons who are in—or are planning to be in—a sexual relationship are tested for HIV together. Additional training is required before any agency or counselor can provide CHTC. Couples go through the entire process together, and receive their results together. *Testing Together* is different from individual testing because it is not focused on past risk behavior, but rather supports couples to address their joint risk concerns with a focus on the present and the future. Couples are only separated if there is suspicion of coercion or to confirm information collected on individual data forms. *Testing Together* is voluntary, and couples may decide at any time during the session that they prefer to be tested separately.

#### Rationale for Testing Together

In 2010, approximately 92% of new HIV diagnoses in the United States were attributed to sexual transmission.<sup>55</sup> In some high-risk groups, this HIV transmission occurs primarily as a result of sex between main partners. Among MSM, for example, it is estimated that as many as 60% to 70% of new HIV transmissions occur within primary partnerships.<sup>56,57</sup> This may be partly due to misperceptions about risk and discordance and to difficulty talking about one's HIV-positive status. One study showed that about 20% of male couples who believed that they were both HIV-negative were actually discordant—that is, one partner was HIV-positive and the other was HIV-negative.<sup>58</sup>

Although sexual transmission is the leading cause of HIV infection in the United States, few prevention efforts have focused on couples or partnered relationships? Consequently, there is a need for improved testing approaches like Testing Together to help reduce HIV transmission among main partners.

#### Benefits of Testing Together

Testing Together was designed to improve HIV prevention, care, and treatment outcomes by creating a safe space for couples to discuss difficult issues, including their joint risk concerns and agreements about sex within and outside their relationship. Couples make plans for the future based on both their HIV test results, as well as their relationship status. Mutual disclosure of HIV status is immediate and 100% with this strategy, and partners can support each other to access care if one or both of them are HIV-positive.

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<sup>55</sup> CDC. Estimated HIV incidence among adults and adolescents in the United States, 2007-2010. *HIV Surveillance Supplemental Report* 2012;17(4). [http://www.cdc.gov/hiv/pdf/statistics\\_hssr\\_vol\\_17\\_no\\_4.pdf](http://www.cdc.gov/hiv/pdf/statistics_hssr_vol_17_no_4.pdf). Accessed March 24, 2016.

<sup>56</sup> Goodreau SM, Carnegie NB, Vittinghoff E, et al. What drives the U.S. and Peruvian HIV epidemics in men who have sex with men (MSM)? *PLoS One* 2012;7(11):e50522.

<sup>57</sup> Sullivan PS, Salazaar L, Buchbinder S, and Sanchez TH. Estimating the proportion of HIV transmissions from main sex partners among men who have sex with men in five U.S. cities. *AIDS* 2009;23(9):1153-1162.

<sup>58</sup> Wagenaar BH, Grabbe KL, Stephenson R, et al. Do men who have sex with men (MSM) in the United States understand that HIV serodiscordance is possible? *Open AIDS J* 2013;7:14-16.

<sup>59</sup> CDC. Compendium of evidence-based interventions and best practices for HIV prevention. <http://www.cdc.gov/hiv/research/interventionresearch/compendium/index.html>. Updated June 2015. Accessed March 24, 2016.

Agencies that actively promote Testing Together services have found great success in reaching first-time testers and diagnosing new HIV infections. Since these are 2 key goals of HIV testing programs, Testing Together is seen as an important high-impact HIV testing strategy.

## Differences from Individual Testing

Testing Together follows a very similar structure to individual HIV testing but with some key differences. These are outlined below:

### Comparing individual HIV testing with Testing Together.

Individual HIV testing	Testing Together
Clients learn their individual HIV status alone.	Clients learn their own HIV status as well as that of their partner(s).
Clients must disclose to their partner on their own, or use PS.	Counselor-facilitated mutual disclosure among partners is immediate and 100%.
Clients deal with issues of tension and blame on their own.	Provider is there to help ease tension and diffuse blame.
Individual risk screening is based on past risk behavior.	Individual risk screening is based on past risk behavior.
Focus is on health education.	Skill building is focused on couple's communication and sexual agreements.
Referrals and linkage are based only on client's HIV status and needs.	Referrals and linkage are tailored to the results and needs of both partners.

## Steps for Conducting Testing Together

The protocol for *Testing Together* looks very similar to the steps for conducting individual HIV testing. Compared to individual testing, which uses a very streamlined approach with minimal counseling, *Testing Together* may require brief counseling in order to establish rapport and enhance their communication as a couple. Similar to individual testing, the format includes "preresults steps" and "postresults steps" that will vary slightly depending on the type of test kit that is being used. Again, for *Testing Together*, we present two scenarios—one for sites using 10-20 minute rapid HIV tests, and one for sites that draw a specimen for laboratory testing or "nonrapid" testing.

## Scenario for conducting *Testing Together*.

<b>Rapid HIV <i>Testing Together</i></b> (15 minute read time for SURE CHECK)	
<b>Preresults steps</b>	
<b>Step 1:</b> Introduce Testing Together and obtain concurrence	
<b>Step 2:</b> Prepare for and conduct rapid HIV test (Use SURE CHECK as the first test—15 minute read time)	
<b>Step 3:</b> Explore couple's relationship	
<b>Step 4:</b> Discuss HIV risk concerns and reasons for seeking testing together	
<b>Step 5:</b> Discuss couple's agreement	
<b>Postresults steps</b>	
<b>Step 6:</b> Provide results of initial rapid HIV test and if positive follow-up with an OraQuick rapid HIV test.	
<b>Step 7:</b> Develop care, treatment, and prevention plan based on results	
<b>Step 8:</b> Refer and link with medical care, social and behavioral services	

## Implementing Testing Together

HIV testing providers must be trained in this approach before offering *Testing Together* services. In the training, providers learn the specific tasks that should be conducted for each step of the *Testing Together* protocol and practice skills-building exercises around couples communication, self-awareness, sexual agreements, and discordant test results. There are also opportunities to practice delivering the steps of the *Testing Together* protocol through role plays. Because of the additional skills required for providing high-quality *Testing Together* services, it is recommended that HIV testing providers have provided individual HIV testing for at least 6 months or to at least 50 individual clients before receiving *Testing Together* training.

The same resources that are used for individual HIV testing can, and should, be used to offer *Testing Together*. All of the information in this Implementation Guide applies to both individual and couples testing, including the need to adhere to program principles and standards, the need for monitoring and evaluating *Testing Together* service delivery, and the need for quality assurance to ensure high-quality service provision. Because *Testing Together* is a new service agencies will need to revisit and revise their targeting and recruitment plans to include couples.

More information about *Testing Together* training and how to access technical assistance for implementation support at your agency is available at: <https://effectiveinterventions.cdc.gov/>. This site also hosts a *Testing Together* toolkit with implementation support materials including videos, marketing materials, manuals, and worksheets.

## Chapter 7

### REFERRAL, LINKAGE, AND NAVIGATION SERVICES

A primary goal of HIV testing in nonclinical settings is to identify clients with undiagnosed HIV infection and link them to HIV medical care as soon as possible. Additionally, HIV testing providers may play a role in the reengagement of previously diagnosed HIV-positive persons who are not currently engaged in care. Referral and linkage to HIV care services and initiation of ART facilitate better health outcomes for HIV-infected persons and can help prevent HIV transmission. Furthermore, HIV-negative persons at substantial risk for HIV infection may also benefit from referral and linkage to care for PrEP, STD testing and treatment, or other information and HIV prevention support. Both HIV-positive and HIV-negative clients may benefit from referral and linkage to other health services, including social and behavioral services as outlined in Chapter 5, and may need assistance navigating the health system in order to access these services.

This chapter discusses referral processes, linkage outcomes, and navigation services, and describes the steps that HIV testing providers can take to facilitate successful referral and linkage to HIV medical care, social, and behavioral services for their clients.

In some nonclinical settings, HIV testing providers may conduct referral and linkage services and, in others, they will refer clients to a linkage navigator or other staff who has this designated role. Keep in mind that there are often multiple factors that influence a client's ability or willingness to accept or access referral services, and it is not always appropriate or recommended to address all of these factors at one time. Referral and linkage is a process. It will likely extend beyond the initial HIV testing session and may warrant multiple visits with the client after they receive their HIV test results. Although you will do your best to support and motivate clients to seek referral services, it is ultimately in their hands to accept these services. In order to effectively implement referral and linkage services, you should be aware of the available and relevant resources to support your clients' health. You should also build partnerships with other health care organizations and community agencies to get your clients the services and care they need.

#### Defining Referral, Linkage, and Navigation

**Referral** is the process by which you actively provide clients with information and assistance in accessing medical care, social, and behavioral services. The referral process includes conducting an initial assessment of the client's needs, identifying and prioritizing those needs based on this assessment, identifying barriers to accessing referral services, developing a plan for accessing referral services with the client, and facilitating his or her access to these referral services.

**Linkage** is the outcome verifying the successful completion of your referral by the client. Linkage includes following up with either clients or providers to confirm linkage and documenting the results. For example, when you confirm and document that a client made it to the first medical appointment within 30 days following the initial diagnosis, this is considered successful linkage.

**Navigation** is the overarching system that includes referral and linkage, but which may also extend beyond these steps to include continuous engagement with clients or patients to ensure they remain engaged in HIV medical care, social, and behavioral services for as long as necessary to support viral suppression and HIV prevention. HIV navigation services are intended to serve both clients living with HIV as well as HIV-negative individuals who are at risk of acquiring HIV. The objectives of HIV navigation services are twofold: (1) to provide direct assistance to clients in accessing services, and (2) to support clients in building the knowledge and skills necessary to access and use the system on their own. This process may require contacting clients or patients on a regular basis to identify and address their barriers to staying engaged in care. Navigation often extends beyond the HIV testing encounter.

## Linkage Staff and Navigators

In some agencies, HIV testing providers will also provide referrals and linkage, but in other agencies, specialized staff will be hired as navigators and dedicated to helping clients with this process. The training and development of navigators (e.g., community health workers, peer advocates, outreach workers, case coordinators) will help facilitate access to and retention in HIV medical care and social and behavioral services. Navigators are sometimes peers—persons living with HIV who have successfully accessed medical, risk reduction, and other services. Additionally, depending on an agency or region's existing systems and programs, navigation services may be performed by several staff members—not just a single person—who may offer assistance at various points along the HIV care continuum.

## Implementing Referral, Linkage and Navigation Services

Regardless of whether a client is newly diagnosed with HIV infection, has been previously diagnosed, or is HIV-negative, the steps for referral, linkage, and navigation follow the same basic process:

1. **Identify and prioritize referral needs:** In collaboration with clients, identify what services are most important for keeping the client healthy and safe and for preventing HIV transmission or acquisition. Prioritize these services based on the client's situation and needs. It may not be possible or appropriate to address all of the client's referral needs at one time, so efforts should be focused on facilitating referrals to services that can have the greatest impact on the client's health and risk reduction.
2. **Develop a plan:** Elicit the client's strengths that can be used to implement the referral plan successfully. Furthermore, help the client identify challenges or barriers he or she might have in completing referrals and develop strategies to overcome these challenges. Together with the client, identify the methods you will use to facilitate a referral and help the client complete this referral. Work out a plan to help the client successfully and regularly access the necessary care and services.
3. **Facilitate access to services:** Provide clients with the information and support they need in order to access referrals. This includes supplying them with provider contact information, cost, hours of service, eligibility information, and processes and timelines for making appointments; help in deciphering insurance and financial information; and support for maintaining strong and ongoing communication with service providers. Scheduling appointments for or with clients, accompanying clients to appointments, providing transportation information and assistance, giving ongoing patient education and motivation, and sending appointment reminders can significantly increase the chance of successful referrals. Also be sure to make referrals that are culturally appropriate with regard to age, gender, race, ethnicity, sexual orientation, and other factors.
4. **Confirm and document linkage:** After a designated period of time, confirm and document linkage to referral services by contacting the referral provider or the client to determine if they accessed these services. Obtain client feedback, if possible. If the client was not successfully linked, attempt to determine the reasons for this and provide additional assistance, if appropriate. If the client was successfully linked, document this in the client's file, chart, or referral log. Electronic tracking systems are used by many organizations to track and document linkage.
5. **Maintain contact with client to support navigation:** Once a client has been successfully linked with HIV medical care, social and behavioral services, it may be necessary to remain in contact with them to help them navigate the health care system and other services they might need. Navigation may include accompanying persons to medical appointments, sending reminders and encouraging messages, providing counseling support, and identifying persons who have dropped out of medical care and helping them get reengaged.

## Referral, Linkage, and Navigation Strategies

Chapter 5 outlines the services that you may refer and link clients to after they receive their results. Step 6 of the individual HIV testing protocol and step 8 in the HIV testing protocol for couples is to refer and link clients to HIV medical care and essential social and behavioral support services.

In order to get clients to these services, CDC supports a number of navigation strategies for helping agencies manage the referral and linkage process. You can learn more about how to access training and technical assistance for these strategies in Chapter 8.

- Antiretroviral Treatment and Access to Services (ARTAS): ARTAS is for linking individuals who have recently been diagnosed with HIV to medical care. ARTAS consists of up to 5 sessions with a client within a 90-day period or until the client is successfully linked to HIV medical care, whichever comes first. A client may be transitioned to a medical case manager for longer-term assistance and support.
- HIV Navigation Services (HNS): A model for helping clients understand the entire range of services across the HIV care continuum, including services for high-risk HIV-negative individuals. It is important to ensure that HNS roles and services complement and do not duplicate existing services, programs, and staffing. HNS is not new, but is a different way of addressing a longstanding challenge of helping clients stay engaged in care by addressing the myriad of issues that might keep them out of care.
- Linkage Case Management: Intensive, short-term assistance to facilitate entry into care. A linkage case manager helps clients to develop a personalized plan to acquire needed services.
- Medical Case Management: Ongoing coordination of medical services and follow-up of a client's medical treatments in order to engage and retain HIV-infected persons in medical care. Some HIV testing providers also operate medical case management programs, often at the same site where HIV testing is provided.
- Outreach and Peer Support: Linkage services provided by and for individuals living with HIV. Through one-on-one and/or group interactions, peers can play an integral role in recruiting HIV-positive persons into services, particularly individuals from hard-to-reach populations, clients who have been reluctant to enter into HIV medical care, or individuals who have left medical care.

Each facility should have a list of community resources available to help meet the needs of their clients, and providers should be familiar with these resources. It may be helpful for HIV testing agencies to establish memorandum of agreement (MOAs) with local referral agencies, to streamline the referral process, to ensure high standards of service delivery, and to hold agencies accountable. Client confidentiality or anonymity must be maintained when making referrals.

## Documenting Referrals and Monitoring Linkage

Referrals and linkage should be offered to all clients based on their needs. Due to funding requirements and resource capacity, agencies may need to prioritize the linkages that they monitor. In line with agency procedures, linkages can be documented in a client's chart or in a centralized referral log. You may wish to collect the following information about each linkage:

- Date and time linkage was made
- Name of staff person linking the client
- Type of linkage service
- Name of linkage service provider
- Type of assistance and/or incentives provided to help the client complete the linkage
- Date linkage was successfully achieved, if applicable

- Reasons that linkage was not successfully achieved, if applicable (e.g., client feedback on challenges to accessing services or satisfaction with services)

If an authorization of release of information was necessary to determine if a client was successfully linked to services, place a copy of the authorization in the client chart. Agencies should regularly monitor data to evaluate the extent to which referral and linkage strategies are successful in linking clients with needed services. This ongoing assessment enables agencies to determine whether referral and linkage practices should be changed to better meet the needs of their clients.

## Tracking linkage to HIV medical care

It is particularly important to track linkages for HIV-positive clients to medical care, and HIV-negative clients to PrEP providers. Agencies should adhere to state and local requirements for tracking and reporting these linkages, which may include periodically reporting the proportion of HIV-positive clients linked to medical care who accessed their first appointment within 30 days.

Two main strategies for monitoring whether clients are successfully linked to follow-up services are (1) provider confirmation and (2) client self-report.

Provider Confirmation: Provider confirmation is the preferred method for confirming linkage. The medical provider is contacted by an HIV testing staff member and asked whether the client accessed services. The provider then confirms "yes" or "no". The provider should also report the date that the client accessed services, if applicable or discuss the reasons why the client hasn't yet come in. It is recommended that HIV testing sites authorize specific staff to track these linkages with medical providers. Likewise, clinics should also assign specific staff to confirm the client's linkage. In the case of linkage to medical care, a physician, clinical social worker, or nurse practitioner is the appropriate authorized party.

Client Self-Report: You may sometimes have ongoing contact or interactions with clients beyond the initial HIV testing event. The next contact with a client after he or she is linked to services provides a good opportunity for asking the client whether he or she successfully accessed the service. This also provides a good opportunity for obtaining client feedback about any challenges they encountered and their satisfaction with the services received. While client self-report is an acceptable means to confirm linkage, clients sometimes tell us what we want to hear rather than what actually happened. For this reason, provider confirmation is the preferred means for confirming linkage.

## Chapter 8

### CONCLUSIONS

HIV testing is a core component of the high-impact prevention approach. To make improvements along the HIV care continuum, to meet the goals of the NHAS, and to reduce the number of new HIV infections occurring each year in the United States, high-quality HIV testing services must be provided to the right populations in a timely way and with a focus on linkage to medical care, social, and behavioral services based on the client's test results and needs. HIV testing is important for identifying persons living with HIV early in their infection and for successfully linking them with medical care and treatment and prevention services. It is also important for identifying high-risk HIV-negative persons and successfully linking them with preventive services and treatment such as nPEP, PrEP, and social and behavioral services.

### Chapter Summary

This Implementation Guide has offered key information and operational guidance for HIV testing providers. We have outlined key principles and standards that all nonclinical HIV testing programs should meet, reviewed the importance of targeting and recruitment for HIV testing services, and provided an overview of HIV tests and testing technologies. We have provided step-by-step instructions for how to conduct an HIV testing session with your clients in nonclinical settings, discussed the importance of testing couples and sexual partners together, and reviewed the key elements of referral, linkage, and navigation services.

### Training and Technical Assistance

After reading this Implementation Guide, you should now have a better understanding of your role as an HIV testing provider and have a greater knowledge of how to conduct high-quality and effective HIV testing services. This guide should continue to serve as a resource to you and other HIV testing staff at your agency as you implement these services.

In addition to providing this Implementation Guide, CDC/DHAP's Capacity Building Branch (CBB) funds Capacity Building Agencies (CBAs) known collectively as the CBA Providers' Network (CPN), who, together with CBB staff, provide free, direct training and technical assistance to community-based organizations, health departments, and health care organizations throughout the United States. CBA is provided for HIV testing and in other HIV prevention program areas. Specifically related to HIV testing, technical assistance may be requested in areas including, but not limited to, the following:

- Screening and testing of all patients/clients for HIV (in clinical settings)
- Screening and testing of all HIV testing patients/clients for STD, TB, and hepatitis
- Routine, early HIV screening and testing of all pregnant women
- Targeting and recruitment for HIV testing (including social marketing, media, outreach)
- Couples and partner HIV testing and counseling (including data support, marketing, quality assurance)
- Integration of HIV testing efforts into existing services
- Partner services
- Referral and linkage to services after screening/testing
- Third-party systems for reimbursement of costs associated with eligible HIV testing services
- Cultural competence
- Collaboration with laboratory and surveillance programs
- Use of home testing
- Pharmacy-based testing

More information about CBA, including instructions for how to request CBA through CDC's CBA Request Information System (CRIS) is available at the CBB website: <http://www.cdc.gov/hiv/dhap/cbb/>.

CRIS can be accessed directly at: <https://wwwn.cdc.gov/Cris2009>.

The High-Impact Prevention Training Calendar and Registration page at the Effective Interventions website lists all CDC-supported trainings for evidence-based interventions (EBIs) and public health strategies, including HIV testing: <http://effectiveinterventions.cdc.gov/en/TrainingCalendar.aspx>. The Training and Events Calendar also lists all trainings offered by the CPN, including those that are not funded by CDC.

The CPN website contains additional information about CBA, including a CPN directory: <http://www.cbaproviders.org/home.aspx>.

## Additional Resources

The following CDC websites contain additional information about topics referenced in this Implementation Guide or related to HIV testing. These sites are updated frequently and should contain the most up-to-date information for your reference:

- Act Against AIDS Media Campaigns: <http://www.cdc.gov/actagainstaids/>.
- Compendium of Evidence-Based Interventions and Best Practices for HIV Prevention: <http://www.cdc.gov/hiv/research/interventionresearch/compendium/index.html>.
- High-Impact HIV Prevention: <http://www.cdc.gov/hiv/policies/hip.html>.
- HIV Basics (information for patients and clients): <http://www.cdc.gov/hiv/basics/index.html>.
- HIV Testing in Clinical Settings: <http://www.cdc.gov/hiv/testing/clinical/index.html>.
- HIV Testing Site Locator: <http://gettested.cdc.gov/>.
- Home HIV Testing: <http://www.cdc.gov/hiv/testing/hometests.html>.
- Laboratory-based HIV Testing: <http://www.cdc.gov/hiv/testing/laboratorytests.html>.
- Nonclinical HIV Testing: <http://www.cdc.gov/hiv/testing/nonclinical/index.html>.
- Partner Services (PS): <http://www.cdc.gov/nchhstp/partners/partner-services.html>.
- Nonoccupational Postexposure Prophylaxis (nPEP): <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5402a1.htm>.
- Preexposure Prophylaxis (PrEP): [http://www.cdc.gov/hiv/pdf/PrEP\\_fact\\_sheet\\_final.pdf](http://www.cdc.gov/hiv/pdf/PrEP_fact_sheet_final.pdf).
- Prevention is Care Campaign: <http://www.cdc.gov/actagainstaids/campaigns/pic/index.html>.

The following non-CDC websites also contain very useful information for HIV testing and other prevention, care, and treatment providers:

- AIDS.GOV, includes provider tools for prevention, care, and treatment: <https://www.aids.gov/>.
- National HIV/AIDS Strategy: <https://www.whitehouse.gov/administration/eop/onap/nhas>.
- Project Inform: <http://www.projectinform.org/>.

## Thank You

Lastly, CDC acknowledges the hard work and dedication of all frontline HIV testing providers, HIV prevention staff, and health care workers in the United States. It is because of your care for the communities you live and work in, your compassion for your patients and clients, and your commitment to working smarter that advances continue to be made in HIV prevention in the United States. Thank you.

## APPENDIXES

### Job Aids for Individual HIV Testing

- Appendix A      PROTOCOL CARD—Rapid HIV Testing for Individuals
- Appendix B      PROVIDER FLIP CARD—Rapid HIV Testing for Individuals
- Appendix C      SCRIPTS—Rapid HIV Testing for Individuals

### Job Aids for *Testing Together* (Couples)

- Appendix D      PROTOCOL CARD—Rapid HIV Testing for Testing Together
- Appendix E      PROVIDER FLIP CARD—Rapid HIV Testing for Testing Together
- Appendix F      SCRIPTS—Rapid HIV Testing for Testing Together
- Appendix G      SURE CHECK Rapid HIV 1/2 Antibody Test INSTRUCTIONS
- Appendix H      OraQuick ADVANCE Rapid HIV 1/2 Antibody Test INSTRUCTIONS
- Appendix I      Kentucky DIS (Disease Intervention Specialists) and HIV Care Coordinators

*\*\*PROTOCOL CARDS can be printed and hung in the HIV testing room to remind providers of the steps for conducting an HIV testing session with clients.*

*\*\*PROVIDER FLIP CARDS can be printed, cut, laminated, and bound (a 1-inch binder ring may be used). Flip cards are a handy "cheat sheet" for HIV testing providers during an HIV testing session with clients. They not only list the main steps of the HIV testing protocol, but also the tasks within each step.*

*\*\*SCRIPTS can be printed double-sided and then studied before and after conducting an HIV testing session with clients. Scripts contain sample language that an HIV testing provider might use to perform each task within the steps of the HIV testing protocol. However, this language should be adapted by the provider so that he or she is comfortable and the words sound natural. It is not advised that providers read the scripts to clients, but rather use them as a reference, as needed.*

# APPENDIX A

## PROTOCOL CARD—*Rapid* HIV Testing for Individuals

## Individual *Rapid* HIV Testing Protocol

<b>1</b>	<b>Introduce and Orient Client to Session</b>
<b>2</b>	<b>Prepare For and Conduct Rapid HIV Test</b> <i>(15-20 minute read time)</i>
<b>3</b>	<b>Conduct Brief Risk Screening</b>
<b>4</b>	<b>Provide Initial Results and Follow Protocol for Second Rapid Test</b>
<b>5</b>	<b>Develop Care, Treatment, and Prevention Plan Based on Results</b>
<b>6</b>	<b>Refer and Link with Medical Care, Social and Behavioral Services</b>

## APPENDIX B

### PROVIDER FLIP CARD—Rapid HIV Testing for Individuals

## Individual *Rapid* HIV Testing Provider Flip Card

### Testing Together Protocol

1	Introduce and Orient Client to Session
2	Prepare For and Conduct Rapid HIV Test ( <i>SURE CHECK</i> ) (15 minute read time)
3	Conduct Brief Risk Screening
4	Provide Initial Results and if + Follow Protocol for Second Rapid HIV Test ( <i>OraQuick</i> ) (20 minute read time)
5	Develop Care, Treatment, and Prevention Plan Based on Results
6	Refer and Link with Medical Care, Social and Behavioral Services



## Individual *Rapid* HIV Testing Provider Flip Card

### STEP 1

#### Introduce and Orient Client to Session

Introduce yourself and describe your role.

Provide brief session overview.

- Timing of session.
- Process for conducting test.
- How results are returned.

Obtain concurrence to proceed with session.

### STEP 2

#### Prepare For and Conduct *SURE CHECK* Rapid HIV Test

Explain process of conducting HIV test:

- Type of test (rapid antibody test).
- Sample collected (fingerstick blood).
- Time until test results are ready (15 minutes).

Explain meaning of positive and negative results:

- Need for retesting if negative.
- Need for follow-up test if positive.
- Possibility of invalid result.

Obtain consent to test (oral or written).

Distribute test kit information booklet (required for CLIA-waived tests).

Collect specimen and conduct rapid HIV test.

## Individual *Rapid* HIV Testing Provider Flip Card

### STEP 3

#### Conduct Brief Risk Screening

Ask how the client decided to be tested; listen and probe for previous testing history and indicators of increased risk:

- Potential exposure in last 24-72 hours.
- Potential exposure in last 3 months.
- Symptoms.
- Ongoing risk behavior or key population (MSM, PWID, partner with unknown or known HIV-positive status, transgender woman).

Address indicators of increased risk and make immediate referrals for nPEP, acute infection testing, or medical care, as indicated.

Assess client's knowledge of HIV transmission, provide accurate information as indicated.

Prepare for possible test results.

### STEP 4

#### Provide Initial Results and Follow Protocol for Second Rapid Test

Confirm readiness to receive results.

Provide clear explanation of results.

##### NON-REACTIVE (HIV-NEGATIVE):

"Your results are HIV-negative. This means the test did not detect HIV antibodies at this time."

##### REACTIVE (HIV-POSITIVE):

"Your results are HIV-positive. This means the test detected HIV antibodies, and it is very likely that you have HIV. We will now provide follow-up rapid testing."

##### INVALID: (*rare*)

"The test is invalid and must be repeated now."

## Individual *Rapid* HIV Testing Provider Flip Card

### STEP 5: HIV-NEGATIVE

#### Develop Care, Treatment, and Prevention Plan Based on Results

Explore client's reaction to result.

Discuss need for retesting based on client's risk.

Emphasize key risk reduction strategies that will help client remain HIV-negative.

- Choose less risky sexual behaviors.
- Get tested for HIV together with partners.
- Use condoms consistently and correctly.
- Reduce number of sex partners.
- Talk to doctor about PrEP.
- Talk to doctor about nPEP as needed.
- Get tested and treated for STDs.
- If partner is HIV-positive, encourage treatment.

Provide condoms.

### STEP 5: HIV-POSITIVE

#### Develop Care, Treatment, and Prevention Plan Based on Results

Explore client's reaction to result.

Advise on next steps for follow-up testing.

Discuss disclosure and inform about processes for partner services.

Advise to access care and treatment for HIV.

- Treatment can help people with HIV live long, healthy lives and prevent transmission. Treatment is recommended for all people with HIV.
- Other health issues can be addressed.

Emphasize key risk reduction strategies that will prevent transmission.

- Choose less risky sexual behaviors.
- Get tested for HIV together with partners
- Use condoms consistently and correctly.
- Reduce number of sex partners.
- Encourage partners to be tested.

Provide condoms.

## Individual *Rapid* HIV Testing Provider Flip Card

### STEP 6

#### Refer and Link with Medical Care, Social and Behavioral Services

##### HIV-NEGATIVE

Identify necessary medical, social, and behavioral referral services:

- nPEP
- PrEP
- Partner or couples HIV testing
- Retesting for HIV
- STD screening and/or treatment
- High-impact behavioral interventions
- Reproductive health services
- Counseling for mental health, substance abuse, domestic violence
- Other social and behavioral services

Make referrals as indicated

Track linkage.

### STEP 6

#### Refer and Link with Medical Care, Social and Behavioral Services

##### HIV-POSITIVE

Identify necessary medical, social, and behavioral referral services:

- HIV care and treatment
- Partner services
- Partner or couples HIV testing
- STD and TB screening and/or treatment
- High-impact behavioral interventions
- Reproductive health services
- Counseling for mental health, substance abuse, domestic violence
- Other social and behavioral services

Make referrals as indicated

Track linkage.

## APPENDIX C

### SCRIPTS—*Rapid* HIV Testing for Individuals

<b>1</b>	<b>Introduce and Orient Client to Session</b>
<b>2</b>	<b>Prepare For and Conduct Rapid HIV Test</b> ( <i>SURE CHECK</i> - 15 minute read time)
<b>3</b>	<b>Conduct Brief Risk Screening</b>
<b>4</b>	<b>Provide Initial Results and Follow Protocol for Second Rapid Test (<i>OraQuick</i> - 20 minute read time)</b>
<b>5</b>	<b>Develop Care, Treatment, and Prevention Plan Based on Results</b>
<b>6</b>	<b>Refer and Link with Medical Care, Social and Behavioral Services</b>

# Individual *Rapid* HIV Testing Scripts: What to Say and Do for Each Step of the Protocol

## Scripts for Conducting Rapid HIV Testing in Nonclinical Settings

<b>STEP 1: Introduce and Orient Client to the Session</b>	
<b>Task 1:</b> Introduce yourself and describe your role	<b>Script:</b> <ul style="list-style-type: none"> <li>Hello, my name is _____, and I will be conducting your HIV test today.</li> </ul>
<b>Task 2:</b> Provide a brief session overview, including: <ul style="list-style-type: none"> <li>How long the session will take</li> <li>Process for conducting the test</li> <li>How results are returned</li> </ul>	<b>Script:</b> <ul style="list-style-type: none"> <li>Before we conduct the test, I will give you some basic information about how the test works. The test takes 15 minutes to develop, and while we wait for the results, we'll talk about what brought you in to get tested today. The entire session shouldn't take more than 30 minutes, and you'll receive your results today.</li> </ul>
<b>Task 3:</b> Obtain concurrence to proceed with the session	<b>Script:</b> <ul style="list-style-type: none"> <li>What questions do you have for me about the session today? Are you ready to get started?</li> </ul>

<b>STEP 2: Prepare for and Conduct Rapid HIV Test (15 minute read time for <i>Clearview</i>)</b>	
<b>Task 1:</b> Explain the process of conducting the rapid HIV test, including: <ul style="list-style-type: none"> <li>Type of test used</li> <li>Sample collected</li> <li>Time until test results are ready</li> </ul>	<b>Script:</b> <ul style="list-style-type: none"> <li>The rapid HIV test we use requires a finger-stick blood sample. I will collect a drop of blood from your finger, place it onto the test kit, and the results will be ready in about 15 minutes. I will have a few more questions for you as the test is developing, and then I will ask you to sit in the waiting room for the remainder of the time until the results are ready.</li> </ul>
<b>Task 2:</b> Explain the meaning of HIV-negative and HIV-positive test results, including: <ul style="list-style-type: none"> <li>Need for re-testing if HIV-negative</li> <li>Need for follow-up testing if HIV-positive</li> <li>Possibility of invalid result</li> </ul>	<b>Script:</b> <ul style="list-style-type: none"> <li>There are two possible test results you might receive today. The first is HIV-negative, which means the test did not detect HIV antibodies at this time and is considered <i>non-reactive</i>. The second is HIV-positive, which means the test did find HIV antibodies, and is considered <i>reactive</i>. A third option is invalid, which is extremely rare. If the test is either invalid or reactive, we will do another test immediately. If the test is non-reactive, you might need to be re-tested also, depending on your risk, which we'll talk about more as the test is developing. What questions do you have for me about the rapid HIV testing procedure?</li> </ul>

## Individual *Rapid* HIV Testing Scripts: What to Say and Do for Each Step of the Protocol

<b>STEP 2:</b> Prepare for and Conduct Rapid HIV Test (15 minute read time for <i>Clearview</i> )	
<b>Task 3:</b> Obtain consent to test (oral or written)	<b>Script:</b> <ul style="list-style-type: none"> <li>If you have no other questions, we can proceed with the HIV test. Do you agree to be tested for HIV today?</li> </ul>
<b>Task 4:</b> Distribute test kit information booklet	<b>Script:</b> <ul style="list-style-type: none"> <li>I also want to give you this information booklet about the test itself. It will answer any additional questions you have about how the test works. Let's get started with the HIV test.</li> </ul>
<b>Task 5:</b> Do fingerstick, collect specimen and conduct rapid HIV test ( <i>Clearview</i> ).	<ul style="list-style-type: none"> <li>Do <i>fingerstick</i>, collect specimen and conduct <i>rapid HIV test (Clearview)</i>.</li> </ul>

<b>STEP 3:</b> Conduct Brief Risk Screening	
<b>Task 1:</b> Ask how the client decided to be tested; listen and probe for previous testing history and indicators of increased risk: <ul style="list-style-type: none"> <li>Potential exposure in last 24-72 hours</li> <li>Potential exposure in last 3 months</li> <li>Symptoms</li> <li>Ongoing risk</li> </ul>	<b>Script:</b> <ul style="list-style-type: none"> <li>What brought you in to be tested for HIV today?</li> <li>Have you been tested for HIV before?</li> <li>Have you had any specific risks recently that you're concerned about? Tell me more about them and when they occurred.</li> <li>Have you had sex without a condom with someone whose HIV status you didn't know, or who you knew was HIV-positive?</li> </ul>

## Individual Rapid HIV Testing Scripts: What to Say and Do for Each Step of the Protocol

<b>STEP 3:</b> <b>Conduct Brief Risk Screening</b>	
<b>Task 2:</b> Address indicators of increased risk and tailor prevention messages to client's situation	<p><u>Script:</u>  <i>If potential exposure in last 24-72 hours, discuss PEP.</i></p> <ul style="list-style-type: none"> <li>Because you mentioned a specific risk of exposure that occurred last night, I want to talk to you about something called 'PEP', or non-occupational post-exposure prophylaxis. PEP is treatment that is only available for persons who were exposed in the last 72 hours. If your results are HIV-negative today, I can refer you to a site where you can get on this treatment to prevent yourself from getting HIV.</li> </ul> <p><i>If potential exposure in last three months, discuss testing for acute HIV infection, condoms, and re-testing.</i></p> <ul style="list-style-type: none"> <li>Because you mentioned a specific risk of exposure that occurred a month ago, I want to talk to you about acute HIV infection. This is the period of time right after infection when there is a lot of HIV in your body, but before your body has had time to develop antibodies to fight the HIV off. HIV is more easily transmitted during this time, and because antibodies haven't yet developed, they might not show up on the tests we use here. If your results are HIV-negative today, you may wish to be re-tested at your doctor using a test that can more accurately detect acute HIV infection. Another option is to use condoms every time you have sex until you can come back here for re-testing, three months from your last potential exposure.</li> </ul> <p><i>If symptoms, discuss importance of accessing medical care.</i></p> <ul style="list-style-type: none"> <li>Because you mentioned that you've experienced some symptoms of HIV infection, it's important for you to know that sometimes people experience symptoms right after they've been infected, and before the body has had time to develop antibodies. If our results are HIV-negative today, it might be important for you to see a doctor and get a test that can more accurately detect acute HIV infection.</li> </ul> <p><i>If ongoing risk, discuss PrEP, condoms, re-testing, partner and couples testing.</i></p> <ul style="list-style-type: none"> <li>Because you mentioned that you have some ongoing risks for HIV, I want to talk to you about the importance of HIV prevention and some new tools we have that can help folks stay HIV-negative. PrEP, or 'pre-exposure prophylaxis', is a treatment that people without HIV take, that can greatly reduce the chances of acquiring HIV. It's still important to use condoms, and to get re-tested for HIV regularly, and your doctor can give you more information about how this works. It's also important to talk about HIV with your sex partners, and to know their HIV status. One way to do that is to come in with your partners and get tested together. When you get tested together we won't ask you about your past risk behavior, we'll just talk about your joint risk concerns, your agreements about sex, and we'll make a plan for your future together. We'll talk more about all of this after you get your results today.</li> </ul>
<b>Task 3:</b> Assess client's knowledge of HIV and how it is transmitted	<p><u>Script:</u></p> <ul style="list-style-type: none"> <li>Tell me what you know about HIV and how it is transmitted.</li> <li>Do you have any questions about HIV transmission that you would like me to answer for you?</li> </ul>

## Individual *Rapid* HIV Testing Scripts: What to Say and Do for Each Step of the Protocol

STEP 3: Conduct Brief Risk Screening	
<p><u>Task 4:</u> Prepare for possible test results</p>	<p><u>Script:</u> <i>Prepare for HIV-negative result</i></p> <ul style="list-style-type: none"> <li>As I already mentioned, your test results today could be HIV-negative or HIV-positive. The tests we use are very accurate, but if you were infected less than three months ago there is a chance the tests won't detect HIV antibodies today. If your test today is HIV-negative, you have a few different options for taking the best care of yourself and your partners. You could go to your doctor or health department and ask for a test that detects acute HIV infection. Those tests are better at detecting very recent HIV infections than those we use here, although even their tests wouldn't detect HIV antibodies if you were only infected a few days ago. Another option is to use condoms every time you have sex until you come back here to get re-tested three months after your last potential exposure.</li> </ul> <p><i>Prepare for HIV-positive result</i></p> <ul style="list-style-type: none"> <li>It is also possible that the test could come back HIV-positive. Have you thought about how you might feel if your test comes back HIV-positive, and who you might share this information with? These days there are lots of options for care and treatment for HIV that can help people live long, healthy lives. If your test result is HIV-positive, we'll do a second type of rapid test just to be sure. Then we'll get you to a medical provider that will do follow-up tests and get you into care. We'll make sure you get the support you need to stay healthy too. We'll connect you with a partner services specialist, who will help you inform your past partners that they may have been exposed to HIV. It's important for them to know so they can make decisions about their own health, but you can remain anonymous in that process if you wish. I know this is a lot to take in, but I want you to be prepared and understand the next steps based on your results today.</li> </ul>
<p><u>Task 5:</u> Summarize discussion, provide motivation and support for addressing HIV risk issues</p>	<p><u>Script:</u></p> <ul style="list-style-type: none"> <li>We have talked about your specific HIV risks and concerns, and I've given you information about HIV prevention, care, and treatment that we will revisit based on your test results today. You made a great decision to come in and get tested for HIV today. It really shows a lot of care for yourself and for those around you. Here's an information booklet for you to have a look at in the waiting area while we wait another few minutes for your results. Do you have any questions for me?</li> </ul>

**Individual *Rapid* HIV Testing Scripts: What to Say and Do for Each Step of the Protocol**

<b>STEP 4: Provide Results</b>	
<u>Task 1:</u> Confirm readiness to receive results	<u>Script:</u> <ul style="list-style-type: none"><li>• Your test results are now ready. Are you ready to hear your results?</li></ul>
<u>Task 2:</u> Provide a clear explanation of results	<u>Script:</u> <p><i>If non-reactive (HIV-negative):</i></p> <ul style="list-style-type: none"><li>• Your results are HIV-negative. This means the test did not detect HIV antibodies at this time.</li></ul> <p><i>If reactive (HIV-positive):</i></p> <ul style="list-style-type: none"><li>• Your results are HIV-positive. This means the test detected HIV antibodies, and it is very likely that you have HIV. But to be sure, we will now provide a second type of rapid test (<i>OraQuick</i>).</li></ul> <p><i>If invalid (extremely rare):</i></p> <ul style="list-style-type: none"><li>• Your results are invalid. This means there was a malfunction, and we must repeat the test now.</li></ul>

## Individual *Rapid* HIV Testing Scripts: What to Say and Do for Each Step of the Protocol

### Results Steps – HIV-Negative Individuals

<b>STEP 5:</b> <b>Develop a Care, Treatment, and Prevention Plan Based on the Results</b>	
<b>Task 1:</b> Explore client's reaction to their results	<b>Script:</b> <ul style="list-style-type: none"><li>• Do you understand your results?</li><li>• How do you feel, now that you've received these results?</li></ul>
<b>Task 2:</b> Revisit risk discussion and reinforce decisions that will help client remain negative: <ul style="list-style-type: none"><li>• Choose less risky sexual behaviors</li><li>• Get tested for HIV together with partners</li><li>• Use condoms consistently and correctly</li><li>• Reduce number of sex partners</li><li>• Talk to doctor about PrEP</li><li>• Talk to doctor about PEP as needed</li><li>• Get tested and treated for STDs</li><li>• If partner is HIV-positive, encourage treatment</li></ul>	<b>Script:</b> <ul style="list-style-type: none"><li>• Now that we have more information about your HIV test results, is there anything about your HIV risk that you would like to discuss again?</li><li>• Have you heard of couples or partner HIV testing? It's an option for testing together with your partner, so that you learn your HIV test results at the same time, with each other.</li></ul>
<b>Task 3:</b> Discuss need for re-testing based on client's risk	<b>Script:</b> <ul style="list-style-type: none"><li>• As we've discussed, I would like you to get re-tested for HIV in 3-6 months.</li></ul>
<b>Task 4:</b> Provide condoms	<b>Script:</b> <ul style="list-style-type: none"><li>• Here are some free condoms – we offer these to all of our clients, and you can always return back here for more when you run out.</li></ul>

## Individual *Rapid* HIV Testing Scripts: What to Say and Do for Each Step of the Protocol

STEP 6: Refer and Link with Medical Care, Social and Behavioral Services		
<p><u>Task 1:</u> Make referrals as indicated; possible referrals include:</p> <ul style="list-style-type: none"> <li>• PEP</li> <li>• PrEP</li> <li>• Partner or couples HIV testing</li> <li>• Re-testing for HIV</li> <li>• STD screening and/or treatment</li> <li>• Behavioral interventions</li> <li>• Reproductive health services</li> <li>• Counseling for mental health, substance abuse and/or domestic violence</li> <li>• Other social and behavioral services</li> </ul>	<p><u>Script:</u></p> <ul style="list-style-type: none"> <li>• Based on our discussion today, I would like to refer you to some additional services that can help you stay healthy, safe, and prevent you from getting HIV in the future.... <i>Discuss relevant services and refer as indicated.</i></li> </ul>	
<p><u>Task 2:</u> Track linkage</p>	<p><u>Script:</u></p> <ul style="list-style-type: none"> <li>• In order to make sure I've done a good job with my referral, and to help you get the services you need, I'm going to contact the healthcare provider in a few weeks to see if you kept your appointment. I'd also like to reach out to you if that's ok with you. Can I take your contact information and follow-up with you in a few weeks?</li> </ul>	

## Results Steps – HIV-Positive Individuals

<b>STEP 5:</b> <b>Develop a Care, Treatment, and Prevention Plan Based on the Results</b>	
<b>Task 1:</b> Explore client's reaction to results	<p><u>Script:</u></p> <ul style="list-style-type: none"> <li>• Do you understand your results?</li> <li>• How do you feel, now that you've received these results?</li> </ul> <p><i>Use silence to explore the client's reaction; attend to their immediate needs before moving on.</i></p>
<b>Task 2:</b> Advise on next steps for follow-up testing	<p><u>Script:</u></p> <p><i>Conduct second rapid test (OraQuick) on-site for follow-up testing:</i></p> <ul style="list-style-type: none"> <li>• As we discussed, your test result today is very accurate. However, we will need to conduct another test for confirmation of this result. In order to get you this result quickly, I will conduct another, different, rapid HIV test here today. We will have the results from this second test in 20 minutes.</li> </ul>
<b>Task 3:</b> Inform about processes for partner services	<p><u>Script:</u></p> <ul style="list-style-type: none"> <li>• Because your test result was HIV-positive today, it is very important that we start to think about who you've come into contact with who might also be infected. It's important that anyone who might have been exposed has the chance to get tested and enrolled in care and treatment if they are also HIV-positive. I'm going to link you with our partner services representative who will have some discussions with you about who might have been exposed. They will contact these persons and let them know about their potential exposure, but they will do so in a way that keeps you anonymous.</li> </ul>

## Individual *Rapid* HIV Testing Scripts: What to Say and Do for Each Step of the Protocol

<b>STEP 5: Develop a Care, Treatment, and Prevention Plan Based on the Results</b>	
<b>Task 4:</b> Advise to access HIV care and treatment: <ul style="list-style-type: none"> <li>• Treatment can prevent transmission and help people with HIV live longer</li> <li>• Other health issues can be addressed with HIV care provider</li> </ul>	<b>Script:</b> <ul style="list-style-type: none"> <li>• It is very important for you to access HIV care and treatment services as soon as possible. Treatment can prevent transmission to other partners, and can help you live a long and healthy life. When we get you linked with a medical provider, you can also discuss other health issues that may be important for managing your HIV infection. Let's talk about what would work best for you, and I can help facilitate linkage with HIV care services.</li> </ul>
<b>Task 5:</b> Revisit risk discussion and reinforce decisions that will prevent transmission <ul style="list-style-type: none"> <li>• Choose less risky sexual behaviors</li> <li>• Get tested for HIV together with partners</li> <li>• Use condoms consistently and correctly</li> <li>• Reduce number of sex partners</li> <li>• Encourage partners to be tested</li> </ul>	<b>Script:</b> <ul style="list-style-type: none"> <li>• I know this is a lot to think about, but it's also important to talk about how we can reduce risk of transmission to others. We don't have to finish this discussion today, but I would like you to think about what might make the most sense for you, and how I can support you with decisions that will prevent transmission.</li> <li>• For example, if you are comfortable having a discussion with your partners about your results today, you can disclose your results to them, or you can come in with your partners for couples HIV testing and counseling, and we can test you both together.</li> </ul>
<b>Task 6:</b> Discuss disclosure and getting support	<b>Script:</b> <ul style="list-style-type: none"> <li>• Are there persons in your life who you would like to share your results with, who can help support you in these next couple of weeks?</li> </ul>
<b>Task 7:</b> Provide condoms	<b>Script:</b> <ul style="list-style-type: none"> <li>• Here are some free condoms – we offer these to all of our clients, and you can always return back here for more when you run out.</li> </ul>

## Individual *Rapid* HIV Testing Scripts: What to Say and Do for Each Step of the Protocol

STEP 6: Refer and Link with Medical Care, Social and Behavioral Services		
<p><u>Task 1:</u> Make referrals as indicated; possible referrals include:</p> <ul style="list-style-type: none"> <li>• HIV care and treatment</li> <li>• Partner services</li> <li>• Partner or couples HIV testing</li> <li>• STD and TB screening and/or treatment</li> <li>• Behavioral interventions</li> <li>• Reproductive health services</li> <li>• Counseling for mental health, substance abuse, and/or domestic violence</li> <li>• Other social and behavioral services</li> </ul>	<p><u>Script:</u></p> <ul style="list-style-type: none"> <li>• As we have discussed, I'm going to refer you to an HIV care specialist who will conduct follow-up testing, and who will get you linked into HIV care services.</li> <li>• I would also like you to talk with our on-site partner services specialist, who will talk to you about previous partners who may have been exposed to HIV.</li> <li>• And finally, based on our discussion today, there are some additional services I would like to refer you to, that will help you stay healthy, safe, and give you the tools you need to prevent HIV transmission.</li> </ul> <p><i>Discuss relevant services and refer as indicated.</i></p>	
<p><u>Task 2:</u> Track linkage</p>	<p><u>Script:</u></p> <ul style="list-style-type: none"> <li>• In order to make sure I've done a good job with my referral, and to help you get the care you need, I'm going to contact the HIV care provider in a few weeks to see if you kept your appointment. I'd also like to reach out to you if that's ok with you. Can I take your contact information and follow-up with you in a few weeks?</li> </ul>	

## APPENDIX D


### PROTOCOL CARD—*Rapid* HIV Testing for Couples Testing Together

<b>1</b>	<b>Introduce Testing Together and Obtain Concurrence</b>
<b>2</b>	<b>Prepare For and Conduct Rapid HIV Test</b> <i>(SURE CHECK - 15 minute read time)</i>
<b>3</b>	<b>Explore Couple's Relationship</b>
<b>4</b>	<b>Discuss HIV Risk Concerns and Reasons for Seeking Testing Together</b>
<b>5</b>	<b>Discuss Couple's Agreement</b>
<b>6</b>	<b>Provide Initial Results and Follow Protocol for Second Rapid Test</b> <i>(OraQuick - 20 minute read time)</i>
<b>7</b>	<b>Develop Care, Treatment, and Prevention Plan Based on Results</b>
<b>8</b>	<b>Refer and Link with Medical Care, Social and Behavioral Services</b>

## APPENDIX E

### PROVIDER FLIP CARD—*Rapid* HIV Testing for Couples Testing Together

## Testing Together *Rapid* HIV Testing Provider Flip Card

Testing Together Protocol	
1	Introduce Testing Together and Obtain Concurrence
2	Prepare For and Conduct HIV Test ( <i>SURE GHECK</i> - 15 minute read time)
3	Explore Couple's Relationship
4	Discuss HIV Risk Concerns and Reasons for Seeking Testing Together
5	Discuss Couple's Agreement
6	Provide Initial Results and Follow Protocol for OraQuick Test
7	Develop Care, Treatment, and Prevention Plan Based on Results
8	Refer and Link with Medical Care, Social and Behavioral Services
	

STEP 1
Introduce Testing Together and Obtain Concurrence
<p>Introduce yourself and describe your role as counselor.</p> <p>Explain Testing Together and discuss benefits.</p> <p>Describe conditions for receiving Testing Together.</p> <ul style="list-style-type: none"> <li>• Partners agree to discuss HIV risk issues and concerns together.</li> <li>• Couple is willing to receive results together.</li> <li>• Couple commits to shared confidentiality; they agree to make disclosure decisions together.</li> </ul> <p>Address expectations, roles, and responsibilities of couple.</p> <p>Provide session overview.</p> <p>Obtain concurrence to receive Testing Together.</p>

## Testing Together *Rapid* HIV Testing Provider Flip Card

### STEP 2

#### Prepare For and Conduct Rapid HIV Test (*10-20 minute read time*)

Explain process of conducting rapid HIV test.

Explain meaning of positive and negative results, including:

- Need for second type of rapid test if positive
- Need for re-testing if negative

Explain possible results for couple

- Both may be HIV-negative
- Both may be HIV-positive
- One may be HIV-positive and the other may be HIV-negative

Obtain consent to test (if required)

Collect specimens and conduct rapid HIV tests

### STEP 3

#### Explore Couple's Relationship

Establish nature and duration of the couple's relationship

Summarize and reflect on the couple's history and their current situation

- Focus on strengths in the relationship

## Testing Together *Rapid* HIV Testing Provider Flip Card

### STEP 4

#### Discuss the Couple's HIV Risk Concerns and Reasons for Seeking Testing Together

Review how the couple decided to receive Testing Together

Assess the couple's feelings associated with receiving Testing Together

Assess the couple's knowledge of HIV and how it is transmitted; when discussing HIV risk:

- Use abstract language
- Remind couple to focus on present and future

Address indicators of increased risk in couple's relationship

Summarize the discussion and provide motivation and support for addressing HIV risk issues.

### STEP 5

#### Discuss Couple's Agreement

Explain concept of agreements in a couple's relationship

Ask couple if they have an agreement

- If yes, encourage couple to describe what their agreement looks like; what are the terms of their agreement
- If no, encourage couple to talk about terms of an agreement they might like to have

Note the relationship between agreement and HIV risk

Engage couple in a role play around how they would like to find out if one partner violated the terms of the agreement

Summarize discussion and reinforce couple's ability to talk openly about their agreement

## Testing Together *Rapid* HIV Testing Provider Flip Card

### STEP 6

#### Provide Initial Results, if + Follow Protocol for OraQuick Test

Confirm readiness to receive results

Provide clear explanation of results

#### CONCORDANT NEGATIVE:

“Your results are the same. You are both HIV-negative. The tests did not detect HIV antibodies.”

#### CONCORDANT POSITIVE:

“Your results are the same. You are both HIV-positive. The tests detected HIV antibodies. We will now provide additional testing to make sure.”

#### DISCORDANT: *deliver HIV-positive test result first.*

“Your test results are different. You are HIV-positive, which means the test detected HIV antibodies. We will now provide additional testing to make sure.”

### STEP 7

#### Develop Care, Treatment, and Prevention Plan Based on Couple's Results

##### CONCORDANT NEGATIVE

Explore couple's reaction to results

Advise on how to keep both partners HIV-negative

- Revisit sexual agreement and reinforce decisions that will help couple remain negative
- Emphasize condom use and reducing number outside partners
- Discuss pre-exposure prophylaxis (PrEP), if appropriate

Discuss need for re-testing

- If recent exposure, re-test in \_\_\_\_ weeks
- If no recent exposure, re-test in 6-12 months

## Testing Together *Rapid* HIV Testing Provider Flip Card

### STEP 7

#### Develop Care, Treatment, and Prevention Plan Based on Couple's Results

##### CONCORDANT POSITIVE

Explore couple's reaction to results

Encourage mutual support and diffuse blame

Advise to access care and treatment for HIV

- Treatment can prevent transmission and help people with HIV live longer
- Other health issues can be discussed with HIV care provider to keep couple healthy

Advise on how to prevent HIV transmission

- Revisit sexual agreement and reinforce decisions that will prevent transmission
- Emphasize condom use and reducing number outside partners
- Encourage outside partners to be tested

Discuss disclosure and getting support

Discuss pregnancy status and desires as needed

### STEP 7

#### Develop Care, Treatment, and Prevention Plan Based on Couple's Results

##### DISCORDANT

Explore couple's reaction to results

Review discordance

Encourage mutual support and diffuse blame

Advise to access care and treatment for HIV

- Treatment can prevent transmission and help people with HIV live longer
- Pre-exposure prophylaxis (PrEP) can prevent HIV acquisition in the negative partner

Advise on how to prevent HIV transmission

- Revisit sexual agreement and reinforce decisions that will prevent transmission
- Emphasize condom use and reducing number outside partners
- Encourage outside partners to be tested

Discuss need for re-testing HIV-negative partner

Discuss disclosure and getting support

Discuss pregnancy status and desires as needed

## Testing Together *Rapid* HIV Testing Provider Flip Card

### STEP 8

#### Refer and Link with Medical Care, Social and Behavioral Services

##### CONCORDANT NEGATIVE

Link the couple with appropriate follow-up services based on their situation and needs, including:

- PrEP
- STI screening and/or treatment
- Behavioral interventions
- Reproductive Health
- Re-testing for HIV
- Counseling for mental health, substance abuse, domestic violence

### STEP 8

#### Refer and Link with Medical Care, Social and Behavioral Services

##### CONCORDANT POSITIVE

Link the couple with appropriate follow-up services based on their situation and needs, including:

- HIV care and treatment
- STI screening and/or treatment
- TB screening
- Partner services
- Behavioral interventions
- Reproductive Health
- Counseling for mental health, substance abuse, domestic violence

## Testing Together *Rapid* HIV Testing Provider Flip Card

### STEP 8

#### Refer and Link with Medical Care, Social and Behavioral Services

##### DISCORDANT

Link the couple with appropriate follow-up services based on their situation and needs, including:

- HIV care and treatment
- STI screening and/or treatment
- TB screening
- Partner services
- PrEP
- nPEP
- Behavioral interventions
- Reproductive Health
- Re-testing for HIV
- Counseling for mental health, substance abuse, domestic violence

## APPENDIX F

### SCRIPTS—Rapid HIV Testing for Testing Together

<b>1</b>	<b>Introduce Testing Together and Obtain Concurrence</b>
<b>2</b>	<b>Prepare For and Conduct Rapid HIV Test (<i>SURE CHECK</i> - 15 minute read time)</b>
<b>3</b>	<b>Explore Couple's Relationship</b>
<b>4</b>	<b>Discuss HIV Risk Concerns and Reasons for Seeking Testing Together</b>
<b>5</b>	<b>Discuss Couple's Agreement</b>
<b>6</b>	<b>Provide Initial Results, if + Follow Protocol for OraQuick Test</b>
<b>7</b>	<b>Develop Care, Treatment, and Prevention Plan Based on Results</b>
<b>8</b>	<b>Refer and Link with Medical Care, Social and Behavioral Services</b>

## Testing Together Rapid HIV Testing Scripts: What to Say and Do for Each Step of the Protocol

STEP 1: Introduce Testing Together and Obtain Concurrence	
<b>Task 1:</b> Introduce yourself and describe your role.	<b>Script:</b> <ul style="list-style-type: none"> <li>Hello, my name is ____, and I will be conducting your Testing Together session today.</li> </ul>
<b>Task 2:</b> Explain Testing Together and discuss benefits.	<b>Script:</b> <ul style="list-style-type: none"> <li>I am happy to see that you have come in together for HIV testing.</li> <li>There are many important benefits associated with receiving HIV Testing Together.</li> <li>Getting tested together allows you to both learn your HIV test results at the same time.</li> <li>You don't have to talk about past risk in this session today, we'll stay focused on the present and the future.</li> <li>You can both learn important information about HIV, and can make decisions together about how to deal with HIV in your lives.</li> </ul>
<b>Task 3:</b> Describe conditions for receiving Testing Together: <ul style="list-style-type: none"> <li>Partners agree to discuss HIV risk issues and concerns together.</li> <li>Partners are willing to receive results together.</li> <li>Partners commit to shared confidentiality</li> <li>Partners agree to make disclosure decisions together.</li> </ul>	<b>Script:</b> <ul style="list-style-type: none"> <li>In order to get the most out of this Testing Together session, it is important that you both agree to a few conditions.               <ul style="list-style-type: none"> <li>First, I need to know that both of you agree to discuss your HIV risk issues and concerns about HIV. I want both of you to feel comfortable expressing your concerns about HIV and getting tested.</li> <li>Second, an important part of getting tested together is receiving your results together. This means that you will know the HIV status of your partner as well as yourself. I need for both of you to agree to receive your results together.</li> <li>Next, I need you to agree to a shared confidentiality. This means your results will only be shared with the two of you, and me as your HIV testing provider.</li> <li>Finally, because you will know each other's HIV status at the end of this session, I need you both to agree to be mindful of how you share your result and the result of your partner. I would like for you to agree that you will not tell anyone else unless you both agree to tell that person. I would also like for you to agree that you will make decisions together about sharing your test results with other people.</li> </ul> </li> <li>Do you have any questions about these conditions?</li> <li>Can you agree to these conditions?</li> </ul>

## Testing Together Rapid HIV Testing Scripts: What to Say and Do for Each Step of the Protocol

<b>STEP 1: Introduce Testing Together and Obtain Concurrence</b>	
<b>Task 4:</b> Address roles and responsibilities of the partners.	<p><b>Script:</b></p> <ul style="list-style-type: none"> <li>• Before we get into the session, I would also like to talk about what is expected of you as individuals and as partners during the Testing Together session.</li> <li>• Some partners find it helpful to establish ground rules for how the session will be conducted, so that we're all in agreement about how to move forward.</li> <li>• Some examples of ground rules that other partners have found helpful are to:             <ul style="list-style-type: none"> <li>○ Participate equally in the discussion.</li> <li>○ Listen carefully and respond to one another.</li> <li>○ Treat each other with respect and dignity.</li> <li>○ Be as open and honest as possible.</li> <li>○ Provide understanding and support to one another.</li> </ul> </li> <li>• What expectations do you have for how the session should be conducted?</li> <li>• Can you agree to the ground rules I mentioned?</li> <li>• Are there any ground rules you would like to establish before we move on with the session?</li> </ul>
<b>Task 5:</b> Provide session overview.	<p><b>Script:</b></p> <ul style="list-style-type: none"> <li>• Let's talk a little about how the session will proceed.</li> <li>• Once you're ready, I will explain the process of conducting the rapid HIV test. Then I will collect the sample so that the test can develop while we continue with the session.</li> <li>• As the test is developing, we will talk a little bit about your relationship so that I can better understand what brought you in for HIV Testing Together.</li> <li>• We will talk about your HIV risk issues and concerns, and then we will spend some time talking about your relationship agreements.</li> <li>• The HIV test results should be ready at that time, and I will give you both your HIV test results together. We will discuss your results, establish a plan for your next steps, and I will answer any questions you have.</li> <li>• The entire session should take between 30-45 minutes.</li> <li>• Do you have any questions about the session?</li> </ul>
<b>Task 6:</b> Obtain concurrence to receive Testing Together.	<p><b>Script:</b></p> <ul style="list-style-type: none"> <li>• We've talked about the conditions for receiving Testing Together, we've talked about your roles and responsibilities, and you have an idea of what the session is going to look like. Are you ready to begin the session?</li> <li>• Are both of you comfortable with what I have said so far, and are you interested in continuing with the session?</li> </ul> <p><i>If yes, proceed. If no, discuss individual HIV testing.</i></p>

## Testing Together Rapid HIV Testing Scripts: What to Say and Do for Each Step of the Protocol

### STEP 2:

#### Prepare for and Conduct Rapid HIV Test (10-20 minute read time)

<p><b>Task 1:</b> Explain process of conducting rapid HIV test.</p>	<p><b>Script:</b></p> <ul style="list-style-type: none"> <li>As I mentioned, we are going to start by conducting the rapid HIV test, so that the test may develop while we proceed with the rest of the session.</li> <li>Let's talk for a minute about the HIV testing process.</li> </ul> <p><i>Explain how you will conduct the HIV rapid test, based on your agency's protocols. Adapt and/or move this step as needed to align with your agency's HIV testing algorithm.</i></p>
<p><b>Task 2:</b> Explain meaning of positive and negative results, including:</p> <ul style="list-style-type: none"> <li>Need for confirmatory test if positive.</li> <li>Need for re-testing if negative.</li> </ul>	<p><b>Script:</b></p> <ul style="list-style-type: none"> <li>Each of you will have your own HIV test result. This result may be either HIV-positive, or HIV-negative.</li> <li>An HIV-positive test result means the test has detected HIV-antibodies in your body.             <ul style="list-style-type: none"> <li>The tests we use are extremely accurate, which means it is highly likely that you have HIV if the test comes back HIV-positive.</li> <li>However, to be sure that this is correct, we will collect another sample for a 2nd type of rapid test. The results of this other test will be available in 20 minutes.</li> </ul> </li> <li>If your test result is HIV-negative, this means that the test did not detect HIV-antibodies.             <ul style="list-style-type: none"> <li>HIV tests are accurate, but they are not able to detect HIV-antibodies if you were infected very recently.</li> <li>We let all HIV-negative partners know that if either of you had a recent exposure, you should be re-tested in ___ weeks to be sure the results are truly negative.</li> <li>Because most partners that get tested together are interested in doing what is most safe for themselves and their partner, they generally decide to use protection during those ___ weeks until they can be re-tested.</li> </ul> </li> </ul>
<p><b>Task 3:</b> Explain possible results for partners.</p> <ul style="list-style-type: none"> <li>Both may be HIV-negative.</li> <li>Both may be HIV-positive.</li> <li>One may be HIV-positive and the other may be HIV-negative.</li> </ul>	<p><b>Script:</b></p> <ul style="list-style-type: none"> <li>Just like each of you will have your own HIV test result, you will also have a test result as partners.             <ul style="list-style-type: none"> <li>It is possible that both of you will be HIV-negative.</li> <li>It is also possible that both of you will be HIV-positive.</li> <li>Finally, it is possible that one of you will be HIV-positive and one of you will be HIV-negative.</li> </ul> </li> <li>Couples frequently receive different HIV test results – where one is HIV-positive and the other is HIV-negative. This happens even when partners have been together for many years, or even when they have children together.</li> <li>There are many factors that can cause partners to have different HIV test results.</li> <li>Do you have any questions about the types of test results you may receive today?</li> </ul>

## Testing Together Rapid HIV Testing Scripts: What to Say and Do for Each Step of the Protocol

<b>STEP 2:</b> Prepare for and Conduct Rapid HIV Test (10-20 minute read time)	
<b>Task 4:</b> Obtain consent to test (if required).	<b>Script:</b> <i>Obtain consent according to your state and/or agency specific policies and procedures.</i>
<b>Task 5:</b> Collect specimens and conduct rapid HIV test.	<b>Script:</b> <i>Collect specimens and conduct rapid HIV test (Clearview) according to your state and/or agency specific policies and procedures.</i>

<b>STEP 3:</b> Explore Couple's Relationship	
<b>Task 1:</b> Establish nature and duration of the couple's relationship.	<b>Script:</b> <ul style="list-style-type: none"> <li>• As we wait for the test to develop, I would like to talk about your relationship.</li> <li>• Can you please tell me a little bit about your relationship?</li> <li>• When and how did you meet?</li> <li>• Do you live together now?</li> <li>• When you look ahead in this relationship, what do you envision?</li> </ul>
<b>Task 2:</b> Summarize and reflect on the couple's history and their current situation. <ul style="list-style-type: none"> <li>• Focus on strengths in the relationship.</li> </ul>	<b>Script:</b> <ul style="list-style-type: none"> <li>• Let me make sure I understand your situation. <i>Summarize what the partners have told you about their history and current situation.</i></li> <li>• Is this correct?</li> </ul>

## Testing Together Rapid HIV Testing Scripts: What to Say and Do for Each Step of the Protocol

<b>STEP 4: Discuss the Couple's HIV Risk Concerns and Reasons for Seeking Testing Together</b>	
<b>Task 1:</b> Review how the partners decided to receive Testing Together.	<b>Script:</b> <ul style="list-style-type: none"> <li>How did you decide to come together for HIV testing today?</li> <li>What brought you in to receive HIV testing services together today?</li> </ul>
<b>Task 2:</b> Assess the partners' feelings associated with receiving Testing Together.	<b>Script:</b> <ul style="list-style-type: none"> <li>How do you both feel about getting tested for HIV and receiving your results together?</li> </ul>
<b>Task 3:</b> Assess the partners' knowledge of HIV and how it is transmitted; when discussing HIV risk: <ul style="list-style-type: none"> <li>Use abstract language.</li> <li>Remind partners to focus on present and future.</li> </ul>	<b>Script:</b> <ul style="list-style-type: none"> <li>Tell me what you understand about HIV and how it is transmitted.</li> </ul> <p><i>Correct any misinformation and ensure accurate understanding of HIV transmission and risk.</i></p> <ul style="list-style-type: none"> <li>Many people in our community have been affected by HIV. The most important thing is to know your HIV status and to take steps in the future to keep yourself healthy and to prevent transmission.</li> </ul>
<b>Task 4:</b> Address indicators of increased risk in the partners' relationship.	<b>Script:</b> <ul style="list-style-type: none"> <li>As we talk about your HIV risk concerns, I want you to remember that it is important for us to stay focused on the present and your future, and to not blame each other for what might have occurred in the past.</li> <li>What specific concerns do you have about HIV and your risk for HIV in your relationship?</li> <li>Have either of you had any symptoms or illnesses that cause you to be concerned that you may have HIV?</li> </ul>
<b>Task 5:</b> Summarize the discussion and provide motivation and support for addressing HIV risk issues.	<b>Script:</b> <ul style="list-style-type: none"> <li>Let me summarize what we've discussed to make sure I understand you correctly.</li> </ul> <p><i>Summarize what the partners have told you about their HIV risk issues and concerns and their reasons for seeking Testing Together.</i></p> <ul style="list-style-type: none"> <li>Is this correct?</li> <li>Is there anything else that I didn't mention that you would like to add?</li> </ul>

## Testing Together Rapid HIV Testing Scripts: What to Say and Do for Each Step of the Protocol

<b>STEP 5: Discuss Couple's Agreement</b>	
<p><u>Task 1:</u> Explain concept of agreements in a couple's relationship.</p>	<p><u>Script:</u></p> <ul style="list-style-type: none"> <li>Many partners have agreements about how they have sex with each other, and with partners outside the relationship.</li> <li>For example, some partners agree that they will only have sex with each other, while others might agree that they can have sex with partners outside the relationship.</li> <li>Some partners might also have rules about how they can have sex with other people, like when, where, and how.</li> </ul>
<p><u>Task 2:</u> Ask partners if they have an agreement.</p> <ul style="list-style-type: none"> <li>If yes, encourage partners to describe what their agreement looks like; what are the terms of their agreement.</li> <li>If no, encourage partners to talk about terms of an agreement they might like to have.</li> </ul>	<p><u>Script:</u></p> <ul style="list-style-type: none"> <li>Do you have an agreement like this in your relationship?</li> </ul> <p><i>If yes:</i></p> <ul style="list-style-type: none"> <li>Can you tell me what your agreement looks like? What are the terms of your agreement?</li> </ul> <p><i>If no:</i></p> <ul style="list-style-type: none"> <li>It's okay to not have an agreement. Many of partners haven't had explicit conversations about an agreement for their relationship.</li> <li>However, a lot of partners also find it useful to develop an agreement, because they can help build trust and reduce risk.</li> <li>What kind of agreement would you like to have for your relationship? What kind of terms would you like to establish for an agreement, if you were to put one in place?</li> <li>Is this something you would like to define today?</li> <li>It's okay if you do not come to a concrete agreement today. I just want to give you a framework for discussing agreements so that you have the skills to have these conversations on your own in the future.</li> </ul>
<p><u>Task 3:</u> Note the relationship between agreement and HIV risk.</p>	<p><u>Script:</u></p> <ul style="list-style-type: none"> <li>It is great that you have an agreement and that you are both on the same page about what is allowed in your relationship and what is not.</li> <li>When discussing your agreement, it is important to note what parts of the agreement support HIV risk reduction behaviors, and which parts of the agreement might lead to riskier behaviors.</li> <li>My goal is not to tell you to change your agreement, but to support you to make decisions that will keep you healthy and prevent HIV transmission.</li> </ul>

## Testing Together Rapid HIV Testing Scripts: What to Say and Do for Each Step of the Protocol

### STEP 5: Discuss Couple's Agreement

#### Task 4:

Engage partners in a role play around how they would like to find out if one partner violated the terms of the agreement.

#### Script:

- In some relationships, even though both partners are on the same page about the terms of their agreement, there comes a time when one or both partners break that agreement.
- I'm not saying that will happen with you, but it is a reality for some couples.

*Ask each partner in turn, starting with "Partner A":*

- Partner A, if Partner B broke your agreement, would you want him (or her) to tell you about it?
- Partner A, how would you want Partner B to tell you if he (or she) broke your agreement? When would you like to know, where would you like him (or her) to tell you, and how would you want him (or her) to say it?
- Be as specific as you can – for example, after work or before work, on the weekend, at the kitchen table, etc.

*Then ask "Partner B":*

- Partner B, if Partner A broke your agreement, would you want him (or her) to tell you about it?
- Partner B, how would you want Partner A to tell you if he (or she) broke your agreement? When would you like to know, where would you like him (or her) to tell you, and how would you want him (or her) to say it?

*Note. The question can be tailored based on the specific agreement that the partners have discussed. The counselor might repeat part of the agreement that has been discussed, for example:*

- "You mentioned before that your agreement allows sex outside your relationship, but only if condoms are used. Partner A, if Partner B ever had sex outside your relationship without a condom, how would you want him to tell you about it?"

#### Task 5:

Summarize discussion and reinforce the couple's ability to talk openly about their agreement.

#### Script:

- Let me summarize what you've told me about your agreement so that we're all on the same page. *Summarize what the partners have told you about their agreement and how they would like to know if the agreement was violated.*
- Is this correct?
- Is there anything else that I didn't mention that you would like to add?

## Results Steps – Concordant HIV-Negative Partners

STEP 6: Provide Initial Results and Follow Protocol for Confirmatory Test – CONCORDANT HIV-NEGATIVE PARTNERS	
<u>Task 1:</u> Confirm readiness to receive results.	<u>Script:</u> <ul style="list-style-type: none"> <li>Your HIV test results are ready. Are you ready to receive your results together?</li> </ul>
<u>Task 2:</u> Provide clear explanation of results.	<u>Script:</u> <ul style="list-style-type: none"> <li>Your HIV test results are the same. They are both HIV-negative. This means the tests did not detect HIV antibodies in either of you today.</li> </ul> <p><i>Adapt messaging based on your agency's HIV testing algorithm and technology used.</i></p> <p><i>If available, show the test results or the test strips to the partners.</i></p>

## Testing Together Rapid HIV Testing Scripts: What to Say and Do for Each Step of the Protocol

### STEP 7:

#### Develop Care, Treatment, and Prevention Plan Based on Results – CONCORDANT HIV-NEGATIVE PARTNERS

<p><b>Task 1:</b> Explore partners' reaction to results.</p>	<p><b>Script:</b></p> <ul style="list-style-type: none"> <li>Do you understand your test results?</li> <li>How do you feel, now that you've received these results?</li> </ul> <p><i>If necessary, allow the partners a few moments of silence to absorb their HIV test results.</i></p>
<p><b>Task 2:</b> Advise on how to keep both partners HIV-negative.</p> <ul style="list-style-type: none"> <li>Revisit sexual agreement and reinforce decisions that will help partners remain negative.</li> <li>Emphasize condom use, reducing number outside partners and testing outside partners.</li> <li>Discuss pre-exposure prophylaxis (PrEP), as appropriate.</li> </ul>	<p><b>Script:</b> <i>Adapt this section based on what partners have already told you.</i></p> <ul style="list-style-type: none"> <li>Since you have both received HIV-negative test results, I would like to talk a little bit further about how to keep you both free from HIV.             <ul style="list-style-type: none"> <li>We previously discussed your agreement about sex in your relationship and with outside partners. Now that we have more information, is there anything about that agreement that you would like to change?</li> <li>As we discussed, using condoms with any outside partners is one of the most effective ways of preventing HIV transmission.</li> <li>Many people also feel better about staying HIV-negative if they are able to reduce the number of outside partners they have.</li> <li>If you do have outside partners, it is also important to know their HIV status. You may want to talk with them about getting tested together.</li> </ul> </li> </ul> <p><i>Adapt discussion of PrEP based on availability in your community.</i></p> <ul style="list-style-type: none"> <li>There have also been recent advances in HIV prevention that I want to tell you about. Studies have shown that when HIV-negative persons take treatment – known as pre-exposure prophylaxis, or PrEP – their chances of acquiring HIV are greatly reduced.</li> <li>If you are interested in learning more about PrEP, I can refer you to a PrEP counselor or provider, who can answer your questions and give you a prescription.</li> </ul>
<p><b>Task 3:</b> Discuss need for re-testing.</p> <ul style="list-style-type: none"> <li>If recent exposure, re-test in _____ weeks.</li> <li>If no recent exposure, re-test in 6-12 months.</li> </ul>	<p><b>Script:</b></p> <ul style="list-style-type: none"> <li>As we discussed at the beginning of this session, your HIV test results today are likely very accurate.</li> <li>However, if either of you have had a recent exposure, you should be retested again in _____ weeks to be sure you are truly HIV-negative. Many partners want to be as safe as possible, and so they opt to get re-tested in _____ weeks to protect themselves and their partner.</li> <li>If you haven't had a recent exposure, we recommend regular retesting every (6–12) months (<i>based on client's risk profile</i>).</li> <li>These recommendations for re-testing are given to all partners who come in and test HIV-negative.</li> </ul>

## Testing Together Rapid HIV Testing Scripts: What to Say and Do for Each Step of the Protocol

### STEP 8:

#### Refer and Link with Medical Care, Social and Behavioral Services – CONCORDANT HIV-NEGATIVE PARTNERS

##### Task 1:

Link the partners with appropriate follow-up services based on their situation and needs, including:

- PrEP
- STI screening and/or treatment
- Behavioral interventions
- Reproductive health
- Re-testing for HIV
- Counseling for mental health, substance abuse, domestic violence

##### Script:

- Based on our discussions today, I would like to link you with the following follow-up services.  
*Adapt this section based on the couple's situation and needs.*  
*Ensure that you are identifying and addressing any barriers the partners might have to seeking follow-up services, and that you are actively linking them with any necessary services by calling ahead, scheduling an appointment, or giving them the name of someone to talk to.*

## Results Steps – Concordant HIV-Positive Partners

STEP 6: Provide Initial Results and Follow Protocol for Confirmatory Test – CONCORDANT HIV-POSITIVE PARTNERS	
<p><u>Task 1:</u> Confirm readiness to receive results.</p>	<p><u>Script:</u></p> <ul style="list-style-type: none"> <li>Your HIV test results are ready. Are you ready to receive your results together?</li> </ul>
<p><u>Task 2:</u> Provide clear explanation of results.</p>	<p><u>Script:</u></p> <ul style="list-style-type: none"> <li>Your HIV test results are the same. They are both HIV-positive. This means the test detected HIV antibodies in both of you today. Next, we will do another type of rapid test just to be sure of these results.</li> </ul> <p><i>Adapt messaging based on your agency's HIV testing algorithm and technology used.</i></p> <p><i>If available, show the test results or the test strips to the partners.</i></p>

## Testing Together Rapid HIV Testing Scripts: What to Say and Do for Each Step of the Protocol

### STEP 7:

#### Develop Care, Treatment, and Prevention Plan Based on Results – CONCORDANT HIV-POSITIVE PARTNERS

<p><b>Task 1:</b> Explore the couple's reaction to results.</p>	<p><u>Script:</u></p> <ul style="list-style-type: none"> <li>• Do you understand your test results?</li> <li>• How do you feel, now that you've received these results?</li> </ul> <p><i>If necessary, allow the partners a few moments of silence to absorb their HIV test results.</i></p> <p><u>Script:</u></p> <ul style="list-style-type: none"> <li>• I understand it can be very hard to receive an HIV-positive test result.</li> <li>• You will probably have many strong feelings about your HIV status and about each other. These feelings are normal, and in time they will get easier to deal with.</li> <li>• You came here today to deal with HIV together. I really want to encourage you to focus now on how you can support each other to get through this tough time.</li> <li>• Remember that HIV infection could have happened at any time. It is difficult to know when and where it came from. The most important thing now is to focus on how to keep you both healthy.</li> <li>• Partner A, why don't you tell Partner B how you're feeling right now?</li> <li>• Partner B, can you tell partner A how you're feeling right now?</li> <li>• Remember that you have dealt with difficult situations in the past, and you're going to get through this. It may take some time to adjust to this new information, but in time, and with each other's support, you will learn to cope and continue living positively together.</li> <li>• There is a lot we have to talk about, but first, do you have any questions?</li> </ul>
<p><b>Task 3:</b> Advise to access care and treatment for HIV.</p> <ul style="list-style-type: none"> <li>• Treatment can prevent transmission and help people with HIV live longer.</li> <li>• Other health issues can be discussed with HIV care provider to keep the partners healthy.</li> </ul>	<p><u>Script:</u></p> <ul style="list-style-type: none"> <li>• Even though your results are HIV-positive, this does not mean that you have AIDS or that you're going to become sick right away.</li> <li>• Remember that although these tests are very accurate, we are going to do a 2nd rapid test for HIV – the results from this test will be available in 20 minutes. <i>(Begin OraQuick and continue with counseling).</i></li> <li>• There is treatment for HIV that can help you live long, healthy, productive lives. Being on treatment also prevents the spread of HIV to partners who are not infected.</li> <li>• When you're ready, we'll get you linked with a health care provider who will work with you to determine which treatments are right for you, and when you should begin taking them.</li> <li>• I know it may seem like a lot to take in, but getting linked with care and treatment is one of the most important things you can do to take care of yourself and each other right now.</li> <li>• What questions do you have about HIV care and treatment?</li> </ul>

## Testing Together Rapid HIV Testing Scripts: What to Say and Do for Each Step of the Protocol

### STEP 7:

#### Develop Care, Treatment, and Prevention Plan Based on Results – CONCORDANT HIV-POSITIVE PARTNERS

<p><b>Task 4:</b></p> <p>Advise on how to prevent HIV transmission.</p> <ul style="list-style-type: none"> <li>• Revisit sexual agreement and reinforce decisions that will prevent transmission.</li> <li>• Emphasize condom use, reducing number outside partners and testing outside partners.</li> <li>• Encourage outside partners to be tested.</li> </ul>	<p><b>Script:</b></p> <p><i>Adapt this section based on what the partners have already told you.</i></p> <ul style="list-style-type: none"> <li>• We previously discussed your agreement about sex in your relationship and with outside partners. Now that we have more information, is there anything about that agreement that you would like to change?</li> <li>• I know this may be the last thing on your mind right now, but there are a few things I want to mention about preventing HIV transmission to other partners.             <ul style="list-style-type: none"> <li>○ As we discussed, using condoms with any outside partners is one of the most effective ways of preventing HIV transmission.</li> <li>○ It can also be important to reduce the number of outside partners you have.</li> <li>○ If you do have outside partners, it is also important to know their HIV status. You may want to talk with them about getting tested together.</li> </ul> </li> </ul>
<p><b>Task 5:</b></p> <p>Discuss disclosure and getting support.</p>	<p><b>Script:</b></p> <ul style="list-style-type: none"> <li>• At the beginning of the session, you both agreed to make decisions together regarding who to tell about your HIV test results.</li> <li>• Many couples find it helpful to identify a person or persons with whom they can share their HIV test results.</li> <li>• Are there any persons in your life that you would like to talk to about your HIV test results today? Who are these people? Do you both agree that these people would be helpful and supportive of you right now?</li> </ul>
<p><b>Task 6:</b></p> <p>Discuss pregnancy status and desires as needed.</p>	<p><b>Script:</b></p> <p><i>Adapt this section based on what the partners have already told you.</i></p> <ul style="list-style-type: none"> <li>• There are many options for partners living with HIV who would like to have children. Just because you have HIV does not mean you cannot have children.</li> <li>• I would encourage you to talk with your HIV care provider about your options, once you are ready.</li> </ul>



## Testing Together Rapid HIV Testing Scripts: What to Say and Do for Each Step of the Protocol

### **STEP 8:**

#### **Refer and Link with Medical Care, Social and Behavioral Services – CONCORDANT HIV-POSITIVE PARTNERS**

##### **Task 1:**

Link the partners with appropriate follow-up services based on their situation and needs, including:

- HIV care and treatment
- STI screening and/or treatment
- TB screening
- Partner services
- Behavioral interventions
- Reproductive health
- Counseling for mental health, substance abuse, domestic violence

##### **Script:**

- Based on our discussions today, I would like to link you with the following follow-up services.

*Adapt this section based on the couple's situation and needs.*

*Ensure that you are identifying and addressing any barriers the partners might have to seeking follow-up services, and that you are actively linking them with any necessary services by calling ahead, scheduling an appointment, or giving them the name of someone to talk to.*

## Results Steps – HIV-Discordant Partners

<b>STEP 6:</b> <b>Provide Initial Results and Follow Protocol for Confirmatory Test – HIV-DISCORDANT PARTNERS</b>	
<b>Task 1:</b> Confirm readiness to receive results.	<b>Script:</b> <ul style="list-style-type: none"> <li>Your HIV test results are ready. Are you ready to receive your results together?</li> </ul>
<b>Task 2:</b> Provide clear explanation of results. <ul style="list-style-type: none"> <li>Deliver HIV-positive test result first, then HIV-negative result.</li> </ul>	<b>Script:</b> <ul style="list-style-type: none"> <li>Your HIV test results are different.</li> <li><i>To the HIV-positive partner:</i> Partner A, your test results are positive, which means your test today detected antibodies to HIV. We will need to do a second type of test to be sure (<i>proceed with OraQuick test</i>).</li> <li><i>To the HIV-negative partner:</i> Partner B, your test results are negative, which means your test today did not detect antibodies to HIV. However, because the tests can't detect infection if it occurred recently, we will want to make plans to re-test you.</li> </ul> <p><i>Adapt messaging based on your agency's HIV testing algorithm and technology used.</i></p> <p><i>If available, show the test results or the test strips to the partners.</i></p>

## Testing Together Rapid HIV Testing Scripts: What to Say and Do for Each Step of the Protocol

### STEP 7:

#### Develop Care, Treatment, and Prevention Plan Based on Results – HIV-DISCORDANT PARTNERS

<p><b>Task 1:</b> Explore the couple's reaction to results.</p>	<p><b>Script:</b></p> <ul style="list-style-type: none"> <li>• Do you understand your test results?</li> <li>• How do you feel, now that you've received these results?</li> </ul> <p><i>If necessary, allow the partners a few moments of silence to absorb their HIV test results.</i></p>
<p><b>Task 2:</b> Review discordance.</p>	<p><b>Script:</b></p> <ul style="list-style-type: none"> <li>• Many couples have different test results, even couples who have been together for a long time.</li> <li>• Remember that there are many factors that contribute to why partners might have different test results.</li> </ul>
<p><b>Task 3:</b> Encourage mutual support and diffuse blame.</p>	<p><b>Script:</b></p> <ul style="list-style-type: none"> <li>• I understand it can be very hard to receive an HIV-positive test result, and as partners, it is difficult to receive different test results.</li> <li>• You will probably have many strong feelings about your HIV status and about each other. These feelings are very natural, and in time they will get easier to deal with.</li> <li>• You came here today to deal with HIV together. I really want to encourage you to focus now on how you can support each other to get through this tough time.</li> <li>• Remember that HIV infection could have happened at any time. It is difficult to know when and where it came from. The most important thing now is to focus on how to keep you both healthy.</li> <li>• Partner A, why don't you tell Partner B how you're feeling right now?</li> <li>• Partner B, can you tell partner A how you're feeling right now?</li> <li>• Remember that you have dealt with difficult situations in the past, and you're going to get through this. It may take some time to adjust to this new information, but in time, and with each other's support, you will learn to cope and continue living positively together.</li> <li>• There is a lot we have to talk about, but first, do you have any questions?</li> </ul>
<p><b>Task 4:</b> Advise to access care and treatment for HIV.</p> <ul style="list-style-type: none"> <li>• Treatment can prevent transmission and help people with HIV live longer.</li> <li>• Other health issues can be discussed with HIV care provider to keep the partners healthy.</li> </ul>	<p><b>Script:</b></p> <ul style="list-style-type: none"> <li>• <i>To HIV-positive partner:</i> Even though your results are HIV-positive, this does not mean that you have AIDS or that you're going to become sick right away.</li> <li>• Remember that although these tests are very accurate, we are going to do a 2nd rapid test for HIV – the results from this test will be available in 20 minutes (<i>proceed with OraQuick test</i>).</li> <li>• There is treatment for HIV that can help you live a long, healthy, productive life. Being on treatment is also one of the most important ways to prevent the spread of HIV to partners who are not infected.</li> <li>• When you're ready, we'll get you linked with a health care provider who will work with you to determine which treatments are right for you, and when you should begin taking them.</li> <li>• I know it may seem like a lot to take in, but getting linked with care and treatment is one of the most important things you can do to take care of yourself and each other right now.</li> <li>• What questions do you have about HIV care and treatment?</li> </ul>

## Testing Together Rapid HIV Testing Scripts: What to Say and Do for Each Step of the Protocol

### STEP 7:

#### Develop Care, Treatment, and Prevention Plan Based on Results – HIV-DISCORDANT PARTNERS

<p><u>Task 5:</u> Advise on how to prevent HIV transmission.</p> <ul style="list-style-type: none"> <li>• Revisit sexual agreement and reinforce decisions that will prevent transmission.</li> <li>• Emphasize condom use, reducing number outside partners and testing outside partners.</li> <li>• Encourage outside partners to be tested.</li> </ul>	<p><u>Script:</u> <i>Adapt this section based on what the partners have already told you.</i></p> <ul style="list-style-type: none"> <li>• We previously discussed your agreement about sex in your relationship and with outside partners. Now that we have more information, is there anything about that agreement that you would like to change?</li> <li>• It is also important to talk about preventing HIV transmission. <ul style="list-style-type: none"> <li>○ As we discussed, using condoms is one of the most effective ways of preventing HIV transmission.</li> <li>○ It is also important to reduce the number of outside partners you have.</li> <li>○ If you do have outside partners, it is also important to know their HIV status. You may want to talk with them about getting tested.</li> </ul> </li> </ul>
<p><u>Task 6:</u> Discuss need for re-testing HIV-negative partner.</p>	<p><u>Script:</u></p> <ul style="list-style-type: none"> <li>• Just as we will do a 2nd rapid test for Partner A, we will also re-test you for HIV, to be sure your results are HIV-negative. This is something we do for all partners of people living with HIV. <i>Proceed with OraQuick.</i></li> </ul>
<p><u>Task 7:</u> Discuss disclosure and getting support.</p>	<p><u>Script:</u></p> <ul style="list-style-type: none"> <li>• At the beginning of the session, you both agreed to make decisions together regarding who to tell about your HIV test results.</li> <li>• Many partners find it helpful to identify a person or persons with whom they can share their HIV test results.</li> <li>• Are there any persons in your life that you would like to talk to about your HIV test results today? Who are these people? Do you both agree that these people would be helpful and supportive of you right now?</li> </ul>
<p><u>Task 8:</u> Discuss pregnancy status and desires as needed.</p>	<p><u>Script:</u> <i>Adapt this section based on what the partners have already told you.</i></p> <ul style="list-style-type: none"> <li>• There are many options for partners living with HIV who would like to have children. Just because you have HIV does not mean you cannot have children.</li> <li>• I would encourage you to talk with your HIV care provider about your options, once you are ready.</li> </ul>



## Testing Together Rapid HIV Testing Scripts: What to Say and Do for Each Step of the Protocol

### STEP 8:

#### Refer and Link with Medical Care, Social and Behavioral Services – HIV-DISCORDANT PARTNERS

##### Task 1:

Link the partners with appropriate follow-up services based on their situation and needs, including:

- HIV care and treatment
- STI screening and/or treatment
- TB screening
- Partner services
- PrEP
- nPEP
- Behavioral interventions
- Reproductive health
- Re-testing for HIV
- Counseling for mental health, substance abuse, domestic violence

##### Script:

- Based on our discussions today, I would like to link you with the following follow-up services.

*Adapt this section based on the partners' situation and needs.*

*Ensure that you are identifying and addressing any barriers the partners might have to seeking follow-up services, and that you are actively linking them with any necessary services by calling ahead, scheduling an appointment, or giving them the name of someone to talk to.*

Laboratory Director: \_\_\_\_\_  
Sign & Date

Site Coordinator: \_\_\_\_\_  
Sign & Date

Procedure approved for initial implementation on \_\_\_\_\_  
Date

( ) Reviewed ( ) Revised: \_\_\_\_\_  
Director Initial & Date

( ) Reviewed ( ) Revised: \_\_\_\_\_  
Director Initial & Date

( ) Reviewed ( ) Revised: \_\_\_\_\_  
Director Initial & Date

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Director Initial & Date

( ) Reviewed ( ) Revised: \_\_\_\_\_  
Director Initial & Date

**Health Department:** \_\_\_\_\_

## **Chembio® SURE CHECK HIV 1 / 2 Assay Test**

### **I. PURPOSE AND PRINCIPLE OF THE TEST**

The Chembio SURE CHECK ® HIV 1/2 assay is a single-use immunochromatographic test for the detection of antibodies to Human Immunodeficiency Virus Types 1 (HIV-1) and Type 2 (HIV-2) in fingerstick whole blood.

Discovered in 1983, the Human Immunodeficiency Virus is a retrovirus and identified as the etiologic agent for the Acquired Immunodeficiency Syndrome (AIDS), and AIDS related complex. AIDS is characterized by changes in the population of T-cell lymphocytes that play a key role in the immune disease system. In the infected individual the virus causes a depletion of a subpopulation of T-cells, called T-helper cells, which leaves these patients susceptible to opportunistic infections and certain malignancies. The major routes of transmission are sexual contact, exposure to contaminated blood products (including sharing of contaminated syringes and needles) and mother-to-newborn transmission.

The HIV virus consists of a genomic RNA molecule protected by a capsid and an envelope. The HIV envelope is the major target for the humoral antibody response. The presence of the virus in patients causes the immune system to elicit the production of antibodies. The detection of these antibodies can be used as a diagnostic tool.

The Chembio SURE CHECK® HIV 1/2 assay utilizes immobilized antigens for the detection of antibodies to HIV-1 and HIV-2, and is a point-of-care test to aid in the diagnosis of infection with HIV-1 and HIV-2.

The Chembio SURE CHECK® HIV 1/2 assay employs a unique combination of specific antibody binding protein which is conjugated to colloidal gold dye particles, and HIV-1/2 antigens which are bound to the solid phase membrane. The capillary (fingerstick) whole blood, is applied to the capillary tip of the Sampler of test device. The Sampler is inserted into the Buffer, which is provided in a sealed vial. The Buffer facilitates the lateral flow of the specimen and test reagents and promotes the binding of the antibodies to the antigen. The specimen/buffer mixture migrates along the test strip by capillary action, reconstituting the conjugate. If present, the antibodies bind to the colloidal gold conjugated antibody binding protein. In a reactive sample, the dye conjugated-immune complex migrates on the nitrocellulose membrane and is captured by the antigens immobilized in the TEST area producing a pink/purple line. In the absence of HIV-1 and HIV-2 antibodies, there is no pink/purple line in the TEST area. The sample continues to migrate along the membrane and produces a pink/purple line in the CONTROL area containing immunoglobulin G antigens. This procedural control serves to demonstrate that specimen and reagents have been properly applied and have migrated through the device.

## II. PROCEDURAL INSTRUCTIONS

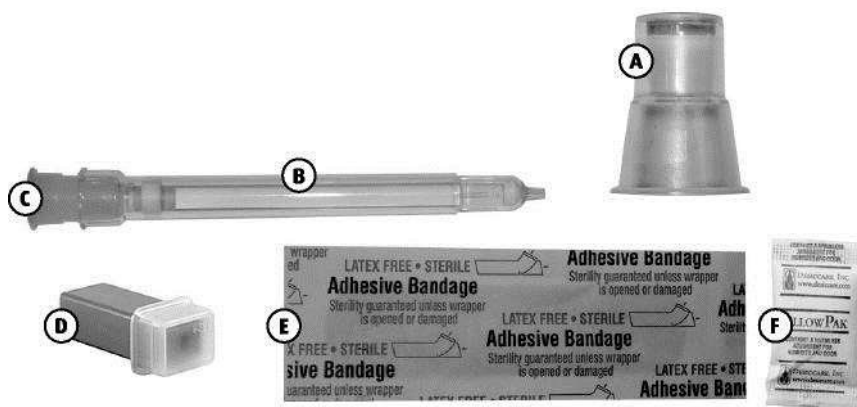
### 1. PREANALYTICAL

<b>KIT CONTENTS AND STORAGE</b>
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#### Material Provided

Each Kit contains the components to perform 25 tests:

- 1 Product Insert for the SURE CHECK® HIV 1/2 assay
- 25 Copies of Subject Information Notice
- 25 Disposable Test Stands (A)
- 25 Pouches, each containing:
  - Sampler with a Test Strip inside (B)
  - Buffer Vial attached to the Sampler (~ 350 µL) (C)
  - Sterile Safety Lancet (D)
  - Bandage (E)
  - Desiccant Packet (F)



### Materials required and available as an accessory to the kit

Chembio HIV Reactive/Nonreactive Controls (Catalog# 60-9549-0).

Each package contains:

- 1 HIV-1 Reactive Control (0.25 mL)
- 1 HIV-2 Reactive Control (0.25 mL)
- 1 Nonreactive Control (0.25 mL)
- 1 Package Insert Chembio Reactive/Nonreactive Controls

### Materials required but not provided

- Transfer Pipette/Weigh Boat set of 36 each (Catalog# 60-9549-1)
- Clock, watch, or other timing device
- Disposable gloves
- Sterile gauze
- Antiseptic wipes
- Biohazard disposal container

### STORAGE INSTRUCTIONS

The Chembio SURE CHECK® HIV 1/2 assay should be stored in its unopened pouch at 8 to 30°C (46 to 86°F). Do not freeze. Do not open the pouch until you are ready to perform a test. When stored as indicated, test devices are stable until the expiration date marked on the pouch.

## QUALITY CONTROL

### ***Built-in Control Features***

The control line serves as a built-in internal control and gives confirmation of sample addition and proper test performance. A pink/purple line will appear in the CONTROL area if the test has been performed correctly and the device is working properly.

(Please see section: *Interpretation of Test Results*).

### ***External Kit Quality Control***

Good Laboratory Practice (GLP) necessitates testing external control material along with the test samples to ensure proper performance of the test Kit. Chembio HIV Reactive/Nonreactive Controls (Catalog#60-9549-0) are available separately for use with the Chembio SURE CHECK HIV 1/2 assay. The HIV Controls are used to verify the operator's ability to properly perform the test and to interpret the results. Each Reactive Control will produce a REACTIVE Test Result and has been manufactured to produce a faint line in the TEST area. The Nonreactive Control will produce a NONREACTIVE Test Result. Run the Controls as per the TEST PROCEDURE and follow the instructions as described in INTERPRETATION OF TEST RESULTS section of the procedure. It is the responsibility of each facility using the Chembio SURE CHECK 1/2 assay to establish an adequate quality assurance program to ensure the performance of the device under specific locations and conditions of use.

### **Storage and Stability of Chembio HIV 1/2 External Controls**

The Chembio HIV Reactive/Nonreactive Controls should be stored at 2 to 8°C (36 to 46°F). Do not use beyond the indicated expiration date. Open the Control Vials only when you are performing tests. Recap and store the Control Vials in their original container at 2 to 8°C (36 to 46°F) in the original Vial.

External control material stored at refrigerated temperatures does not need to be brought to operating temperature (18 to 30°C: 64 to 86°F) prior to testing.

### **Materials Provided in External Control Box**

1. One HIV-1 Positive Control- a red-capped vial
2. One HIV-2 Positive Control- a green-capped vial
3. One Negative Control- a white-capped vial
4. Package Insert

## When to perform Kit Controls under the following circumstances:

- Each new operator prior to performing testing on patient specimens.
- When opening a new test Kit lot.
- Whenever a new shipment of test kits is received.
- If the temperature of the test kit storage area falls outside of 8°-30°C (46°-86°).
- If the temperature of the testing area falls outside of 18°-30°C (64°-86°)
- After two consecutive invalid test results on a patient test.
- Whenever a patient result does not correlate with clinical symptoms and when operator/technician deems necessary.

## 2. ANALYTICAL

### SET UP YOUR WORKSPACE

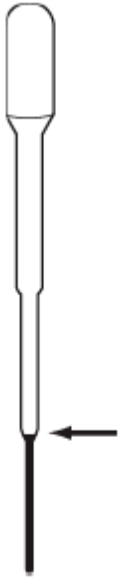
- Gather the materials you will need
- Refer to the External Quality Control section in this procedure to determine when the Kit Controls should be run.
- Cover you workspace with a clean, disposable, absorbent workspace cover.
- Put on PPE

### EXTERNAL CONTROL PROCEDURE

1. Open a Control Vial containing the Control Reagent. **Note:** The Control Reagents are clear to straw-colored. Do not use if the Control Reagent appears visually cloudy or discolored.
2. Remove the Buffer Vial- separate from top of Sampler and place in a Disposable Test Stand provided with Chembio SURE CHECK® HIV 1/2 Assay.

3.

- a. Using a transfer pipet (order no. 60-9549-1) draw the Control Reagent into the pipet to the position shown. To draw up the sample, squeeze the pipet bulb very gently to avoid drawing up too much control material. **NOTE:** The Kit Control reagents are clear to straw-colored. Do not use if the reagent appears visually cloudy or discolored.
  - b. Carefully dispense one drop of the Control Reagent into the weigh boat or a clean, dry surface.
  - c. Touch the tip of the Sampler to the drop of Control Reagent allowing the reagent to travel into the Sampler tip.
  - d. Use a separate pipet and weigh boat for each Control Reagent.
4. With Buffer Vial in Disposable Test Stand, firmly press the Sampler tip through foil cover. Press hard until the Device is fully seated in the Buffer Cap. It will “snap” 3 times when properly seated.
- Snap 1: through foil
  - Snap 2: into the cap
  - Snap 3: fully seated
5. Start timing- wait for 15 minutes. Read the Test Results between 15 and 20 minutes. In some cases a test line may appear in less than 15 minutes, however, 15 minutes are needed to report a Nonreactive Test result. Read Test Results in a well-lit area. **Do not read Test Results after 20 minutes.**
6. Discard all test materials including the Test Device into a biohazard waste container.
7. Reseal the Control Reagent Vials and store them in their original container at 2 to 8°C (36 to 46°F).
8. **Repeat all steps beginning with step 1 of Control Preparation** using the next external control (Negative or HIV-1 Positive or HIV-2 Positive) device.
9. Record all QC on the Chembio SURE CHECK® HIV 1/2 assay QC log.
10. See Interpretation of Test Results below.



**NOTE:** IF the Test Result for the Nonreactive Control, HIV 1 reactive Control or HIV 2 Reactive Control is not as expected, the test should be repeated using a new Test Device and Control Specimen. IF the HIV Control Reagents do not produce the expected results, contact Chembio Diagnostic Systems Customer Service at (631) 924-1135 or Toll Free 1-800-327-3635 if you are unable to obtain a valid Test Result upon repeat testing.

## SPECIMEN COLLECTION AND TESTING PROCEDURE

Prior to specimen collection, provide test subjects with Subject Information Notice and pre-test counseling according to CC Guidelines for Rapid HIV Testing.

### Fingerstick Whole Blood Specimen Collection: (CLIA waived testing)

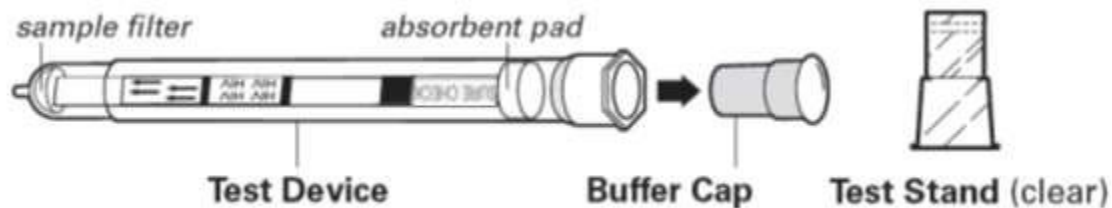
Prepare to perform the fingerstick blood collection procedure.

1. Clean the finger of the person being tested with an antiseptic wipe.
2. Allow the finger to dry thoroughly or wipe dry with a sterile gauze pad.
3. Using a sterile lancet, puncture the skin just off the center of the finger and wipe away the first drop with sterile gauze and avoid squeezing the fingertip to accelerate bleeding as this may dilute the blood with excess tissue fluid.
4. Collect the sample from the second drop touching the Sampler tip of the device to the drop of blood until the Sampler tip is full.
5. Test immediately, following Test Procedure Instructions

## Testing Procedure

All components for the Chembio SURE CHECK® HIV 1/2 assay are ready to use as supplied. Follow directions as indicated.

### 1. OPEN POUCH, REMOVE AND IDENTIFY COMPONENTS

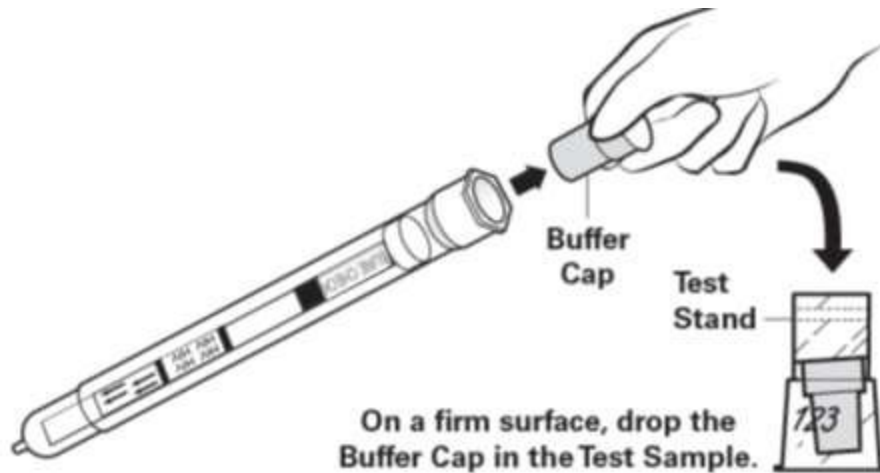


**Note:** If Desiccant Packet is missing or if absorbent pad (at top of Sampler) is missing or if sample filter (at bottom of Sampler) is missing, DO NOT USE. Discard device and use a new device.

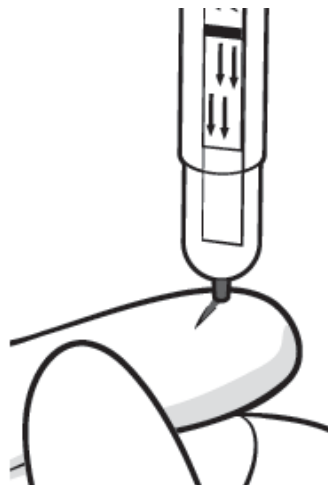
### 2. WRITE PATIENT ID ON STAND

### 3. SEPARATE BUFFER CAP FROM TEST DEVICE

#### 4. PLACE BUFFER CAP IN TEST STAND



#### 5. SPECIMEN APPLICATION- for fingerstick whole blood, touch blood drop with Sampler tip until the tip is full.

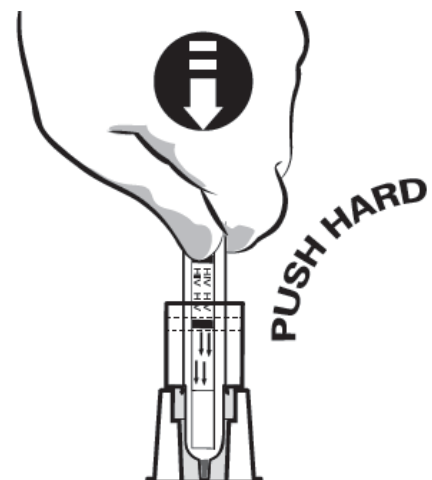


#### 6. START THE TEST

- With Buffer Cap in Stand, firmly press the Device tip through foil cover.
- Push hard until Device is fully seated in the Buffer Cap.

It will “snap” 3 times when properly seated.

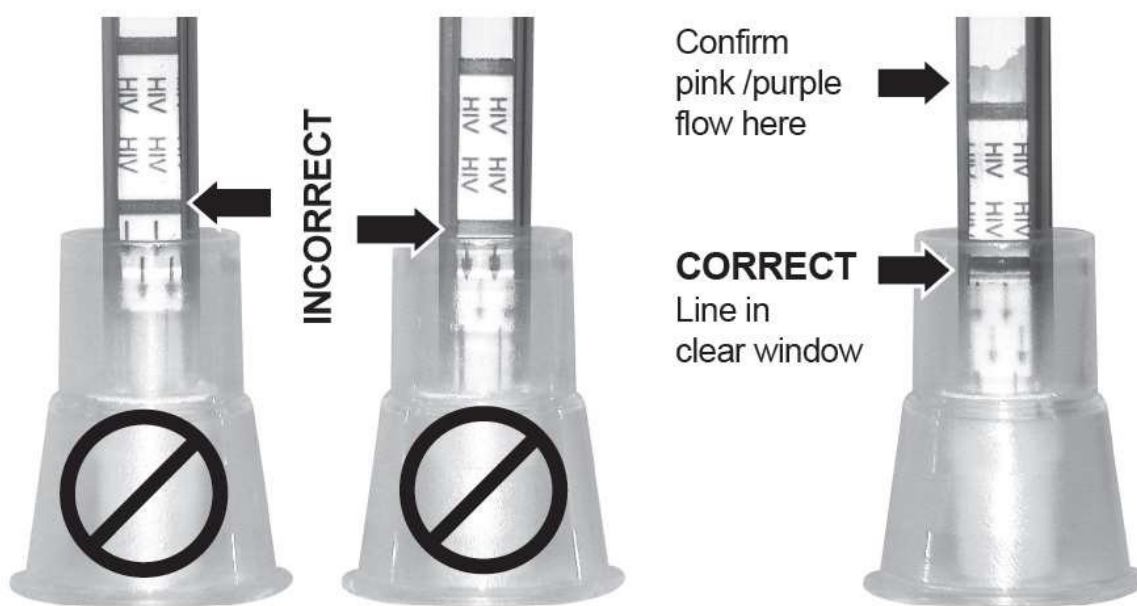
- Snap 1: through foil
- Snap 2: into cap
- Snap 3: fully seated



## 7. CONFIRM DEVICE IS FULLY SEATED

- The blue line directly above the arrows must line up with the clear line in the Stand
- You will see pink/purple Buffer solution begin to flow upwards

**IF YOU DO NOT SEE PINK/PURPLE FLOW WITHIN 3 MINUTES, PUSH AGAIN (then start timer)**



## 8. START TIMING- WAIT FOR 15 MINUTES

**NOTE:** the sampler/buffer Vial should be kept upright in the Test Stand



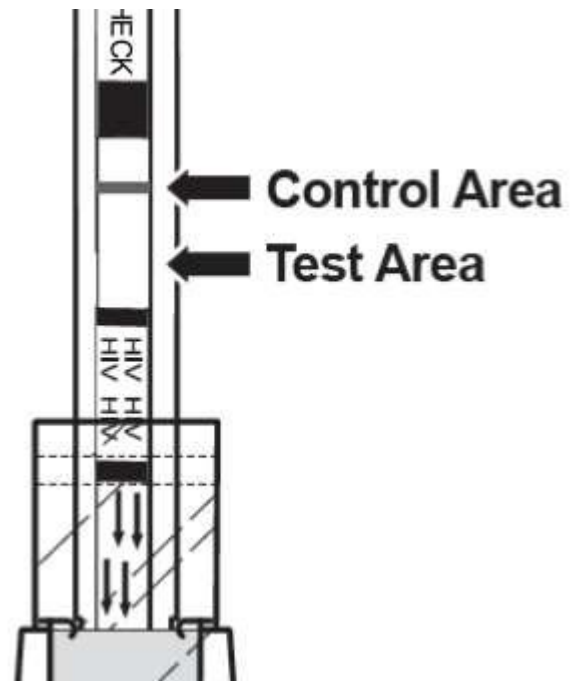
**15 minutes**

## 9. READ TEST RESULTS

Read the test between 15 and 20 minutes.

NOTE: Reactive Test Results (See interpretation of Test Results section) may be observed and read earlier than 15 minutes. To verify a Nonreactive Test Result, wait the entire 15 minutes.

**Do not read results after 20 minutes.**



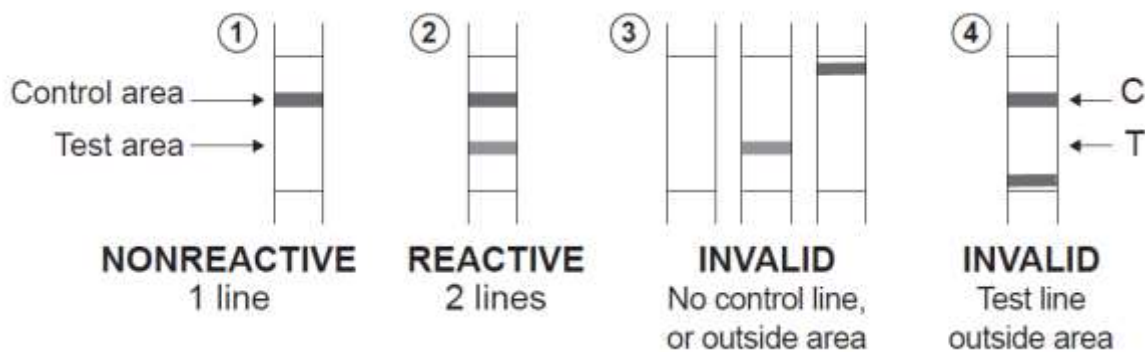
### GENERAL TEST CLEAN-UP

1. Dispose of the used test materials in a biohazard waste container.
2. When using gloves, change your gloves between each test to prevent contamination. Throw away the used gloves in a biohazard waste container.
3. Use a freshly prepared 10% solution of bleach to clean up any spills.

### INTERPRETATION OF TEST RESULTS

When the Chembio SURE CHECK® HIV 1/2 assay is properly performed, the appropriate pink/purple lines will become visible. These are:

1. **The CONTROL LINE-** which appears closer to the top of the test strip, indicates that specimen was adequately applied, and there was proper hydration and migration of reagents. The control line will become visible within 15 minutes after starting the test regardless of the HIV antibody status of the specimen.
2. **The TEST LINE-** which appears closer to the bottom of the test strip (below the control line) indicates the presence of HIV-specific antibodies. The test line will only become visible within 15 minutes after starting a valid test when HIV specific antibodies are present at detectable levels in the specimen.



### **NON-REACTIVE (diagram 1):**

One pink/purple line in the CONTROL area, with no line in the TEST area indicates a NONREACTIVE Test Result. A NONREACTIVE Test Result means that HIV-1 and HIV-2 antibodies were not detected in the specimen. The test Result is interpreted as **NEGATIVE for HIV-1 and HIV-2 antibodies**. However, this does not exclude possible infection with HIV. Follow CDC guidelines to inform the test subject of the Test Result and its interpretation.

### **REACTIVE (diagram 2)**

Two pink/purple lines, one in the TEST area and one in the CONTROL area indicate a REACTIVE Test Result. The line in the TEST area may look different from the line in the CONTROL area. Intensities of the Test and Control Lines may vary. Test Result with visible lines in both TEST and CONTROL areas, regardless of intensity, is considered REACTIVE. A REACTIVE Test Result means that HIV-1 and/or HIV-2 antibodies have been detected in the specimen. The Test Result is interpreted as **Preliminary POSITIVE for HIV-1 and/or HIV-2 antibodies**. Follow CDC guidelines to inform the test subject of the Test Result and its interpretation.

### **INVALID (diagram 3)**

A pink/purple line should always appear in the CONTROL area, whether or not a line appears in the TEST area. If there is no distinct pink/purple line visible in the CONTROL area, (see diagrams 1 and 2), then the test is INVALID. Any line that appears outside of the Control Area or Test Area (see diagram 3) is an INVALID test. An INVALID test cannot be interpreted. It is recommended that the INVALID test be repeated with a new device.

### **INVALID (diagram 4)**

One pink/purple line in the CONTROL area, with Test line outside the TEST area, then test is INVALID. It is recommended that the INVALID test be repeated with a new device.

### 3. POST ANALYTICAL

#### REPORTING RESULTS

Test results are recorded on the patient's medical record by using the CH-12 form. Refer to testing procedure above. Patient result will be circled to indicate that the test kit built in internal control performed properly (pink/purple line at "C" area and background clear).

#### MEDICAL MANAGEMENT

Follow specific Department for Public Health Core Clinical Service Guide for Medical Management.

#### WARNINGS

##### For *IN VITRO* Diagnostic Use

1. Read the package insert completely before using the product. Follow the instructions carefully as not doing so may result in inaccurate Test Results.
2. Users of this test should follow the CDC Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and other Blood-borne Pathogens.
3. Use of this test Kit with specimens types other than specifically approved for use with this device may result in inaccurate Test Results.
4. This test is CLIA-waived for use only with fingerstick whole blood and venipuncture whole blood samples.
5. This test should be performed at 18°- 30°C (64°- 86°F). If stored refrigerated, ensure that the pouch is brought to operating temperature before performing testing.
6. If the test kit is stored at temperatures outside the storage temperature 8 to 30°C (46 to 86°F), or used outside the operating temperature 18 to 30°C (64 to 86°F), use the Kit Controls to ensure proper performance of the test.
7. Individual infected with HIV-1 and/or HIV-2 who is receiving highly active antiretroviral therapy (HAART) may produce false negative results.

#### PRECAUTIONS

##### Safety Precautions

1. Handle the specimens and materials contacting specimens as if capable of transmitting infection.
2. Do not drink, eat, or smoke in areas where specimens and kit reagents are handled. Avoid any contact with hands, eyes or mouth during specimen collection and testing.
3. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when handling specimens.
4. Dispose of all specimens and materials used in the test procedure in a biohazard waste container. Lancets should be placed in a puncture-resistant container prior to disposal. The recommended method of disposal of biohazard waste is autoclaving

for a minimum of 1 hour at 121°C. Disposable materials may be incinerated. Liquid wastes may be mixed with appropriate chemical disinfectants. A freshly prepared solution of 10% bleach (0.5% solution of sodium hypochlorite) is recommended. Allow 60 minutes for effective decontamination. NOTE: Do not autoclave solutions that contain bleach.

5. For additional information on biosafety, refer to “Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and other Blood-borne Pathogens” and “Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis”.
6. Use 10% bleach or other appropriate disinfectant to wipe all spills. The bleach solution should be made fresh each day.

### Handling Precautions

1. The Chembio SURE CHECK® HIV 1/2 Assay device has a sample filter in the lower part of the device and an absorbent pad in the upper part of the device within the barrel that encloses the test strip. Confirm the presence of the sample filter and absorbent pad prior to performing the test. If either is missing, **DO NOT USE**.
2. Do not use any device if the pouch has been perforated. Do not use the device if the Desiccant Packet is missing.
3. Each device is for single use only.
4. Do not use the reagents beyond the expiration date printed on the pouch. Always check expiration date prior to testing.
5. Do not mix reagents from different lot numbers of Kits.
6. To ensure accurate Test Results, the Sampler must be inserted into the Buffer Vial immediately after the sample application.
7. Adequate lighting is required to read the Test Results.

### LIMITATIONS

1. The Chembio SURE CHECK® HIV 1/2 test must be used in accordance with the instructions in the Package Insert to obtain an accurate result.
2. The Chembio SURE CHECK® HIV 1/2 Assay must be used with capillary (fingerstick) or venous whole blood (for CLIA Waived Testing) only.
3. Reading Nonreactive Test Results earlier than 15 minutes or any Test Result later than 20 minutes may yield erroneous results.
4. Do not open the sealed foil pouch until just prior to use.
5. Do not use Kit contents beyond labeled expiration date.
6. For the collection of the fingerstick whole blood specimen, ensure that the finger is completely dry before performing fingerstick.
7. Read results in a well-lit area.
8. A Reactive Test Result using the Chembio SURE CHECK® HIV 1/2 test suggests the presence of antibodies to HIV-1 and/or HIV-2 in the specimen. The Chembio SURE CHECK® HIV 1/2 Assay is intended as an aid in the diagnosis of infection with HIV-1/2. AIDS and AIDS-related conditions are clinical syndromes and their diagnosis can only be established clinically.

9. For a Reactive Test Result, the intensity of the test line does not necessarily correlate with the titer of antibody in the specimen.
10. A person who has antibodies to HIV-1 or HIV-2 is presumed to be infected with the virus, except that a person who has participated in an HIV vaccine study may develop antibodies to the vaccine and may or may not be infected with HIV.
11. A Nonreactive Test Result does not preclude the possibility of exposure to HIV or infection with HIV. An antibody response to recent exposure may take several months to reach detectable levels.
12. This assay has not been evaluated for newborn screening, cord blood specimens, or individuals less than 13 years of age.

## **PROBLEM SOLVING**

If the correct control results are not obtained, do not report patient results. The test should be repeated using a new Test Device and Control Specimen. If the HIV Control Reagents do not produce the expected results, contact Chembio Diagnostic Systems Customer Service at (631) 924-1135 or Toll Free 1-800-327-3635 for Technical Assistance.

## **III. REFERENCES**

Centers for Disease Control and Prevention (CDC), Department for Health and Human Services, “*Quality Assurance Guidelines for Testing Using Rapid HIV Antibody Waived Under the Clinical Laboratory Improvement Amendments of 1988*”,  
[http://www.cdc.gov/hiv/topics/testing/resources/guidelines/qa\\_guide.htm](http://www.cdc.gov/hiv/topics/testing/resources/guidelines/qa_guide.htm), July 24, 2007

SURE CHECK® HIV 1/2 Assay Kit package insert, Chembio Diagnostic Systems, Inc., 3661 Horseblock Road, Medford, NY 11763; 10-6207-0 Rev 3 April 2016

Chembio HIV Reactive/Nonreactive Controls HIV Rapid Test Control Pack, Chembio Diagnostic Systems, Inc., 3661 Horseblock Road, Medford, NY 11763; 10-6187-0 Rev 10 April 2016

## **IV. AUTHOR**

Robin Cotten, MT (ASCP) June 2016

Linda Dailey MT (ASCP) September 2013

## V. PROCEDURE POLICY, APPROVAL AND REVIEW PROCESS

1. The procedure is to be placed in the SOPM.
2. Each procedure will be initially reviewed and approved with signature by the Director prior to implementation.
3. Each procedure will be reviewed annually and as needed for necessary revision. Any modification will be reviewed and approved as stated in #2 above.
4. Implementation of new or revised procedures must be communicated to all testing personnel prior to the implementation date. The Director must document that each of the testing personnel (by individual name) have been made aware of the procedure changes, revision implementation date and been trained as necessary.
5. Any associated logs, specimen collection instructions or other documents related to the procedure change must be initiated.
6. Each procedure must have a master file. The master file serves as the documented history of the procedure, showing all revisions and the dates used and discontinued or retired.
7. The master file must be maintained for a least two (2) years from last date used.

## VI. APPENDIX

Chembio SURE CHECK HIV-1/2 QC log

## VII. PROCEDURE HISTORY

<i>Revision Date:</i>	<i>Initials:</i>	<i>Pages Affected:</i>	<i>Description of Change(s):</i>

# Chembio SURE CHECK® HIV 1/2 Assay Control Log

*\*\*Begin a new log with each new lot number of testing kits\*\**

Reagent Name: SURE CHECK® HIV 1/2      Kit Lot #: \_\_\_\_\_ (from box)      Exp. Date: \_\_\_\_\_

Control Name: SURE CHECK® HIV 1/2      Lot #: \_\_\_\_\_ (from box)      Exp. Date: \_\_\_\_\_

External Controls: Chembio SURE CHECK	Lot # (on bottle of control material)	Mfg Exp Date	Date Opened
Nonreactive Control			
HIV-1 Reactive Control			
HIV-2 Reactive Control			

Date	Reason for Control	Nonreactive Control		HIV -1 Reactive Control		HIV-2 Reactive Control		P/F	Tech	Comments- Corrective Actions
		√ Internal control ("C" pink/purple line present-background clear)	Result	√ Internal control ("C" pink/purple line present-background clear)	Result	√ Internal control ("C") line present-background clear)	Result			

**Reason for running controls:** **SCH-** scheduled; **OP-** new operator; **LOT-** new test kit lot #; **SHIP-** new ship date; **STORE-** temp out of range; **TEMP-** temperature of testing area out of range; **OTHER-** Other, please describe

Site Coordinator: \_\_\_\_\_ Date: \_\_\_\_\_

Lab Director: \_\_\_\_\_ Date: \_\_\_\_\_

Laboratory Director: \_\_\_\_\_  
Sign & Date

Site Coordinator: \_\_\_\_\_  
Sign & Date

Procedure approved for initial implementation on \_\_\_\_\_  
Date

( ) Reviewed ( ) Revised: \_\_\_\_\_  
Director Initial & Date

( ) Reviewed ( ) Revised: \_\_\_\_\_  
Director Initial & Date

( ) Reviewed ( ) Revised: \_\_\_\_\_  
Director Initial & Date

( ) Reviewed ( ) Revised: \_\_\_\_\_  
Director Initial & Date

( ) Reviewed ( ) Revised: \_\_\_\_\_  
Director Initial & Date

**Health Department:** \_\_\_\_\_

## **OraQuick Advance Rapid HIV 1 / 2 Antibody Test PROCEDURE INSTRUCTIONS**

### **I. PURPOSE AND PRINCIPLE OF THE TEST**

The OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test is a manually performed, visually read, 20 minute immunoassay for the qualitative detection of antibodies to HIV-1 and HIV-2 in human oral fluid or whole blood obtained from a finger puncture. The OraQuick *ADVANCE*® rapid test is comprised of a single-use test device and a single-use vial containing a pre-measured amount of a buffered developer solution. Each component is sealed in separate compartments of a single pouch to form the test. The OraQuick *ADVANCE*® rapid test utilizes a proprietary lateral flow immunoassay procedure. The device plastic housing holds an assay test strip comprised of several materials that provide the matrix for the immunochromatography of the specimen and the platform for indication of the test results.

The assay test strip, which can be viewed through the test device result window, contains synthetic peptides representing the HIV envelope region and a goat anti-human IgG procedural control immobilized onto a nitrocellulose membrane in the Test (T) zone and the Control (C) zone, respectively.

An oral fluid specimen is collected using the flat pad on the test device, followed by the insertion of the test device into the vial of developer solution. A fingerstick whole blood specimen is collected and transferred into the vial of developer solution, followed by the insertion of the test device. The developer solution facilitates the flow of the specimen into the device and onto the test strip. As the diluted specimen flows through the device, it rehydrates the protein-A gold colorimetric reagent contained in the device. As the specimen continues to migrate up the strip, it encounters the “T” zone. If the specimen contains antibodies that react with the antigens immobilized on the nitrocellulose membrane, a reddish-purple line will appear, qualitatively indicating the presence of antibodies to HIV-1 and/or HIV-2 in the specimen. The intensity of the line color is not directly proportional to the amount of antibody present in the specimen.

Further up the assay strip, the sample will encounter the “C” zone. This built-in procedural control serves to demonstrate that a specimen was added to the vial and that the fluid has migrated adequately through the test device. A reddish-purple line will appear in the “C” zone during the performance of all valid tests, whether or not the sample is positive or negative for antibodies to HIV-1 and/or HIV-2 (refer to the *Test Result and Interpretation of Test Result* section below).

The test results are interpreted after 20 minutes but not more than 40 minutes after the introduction of the test device into the developer solution containing the test specimen. No precision pipeting, predilutions, or specialized instrumentation are required to perform the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test.

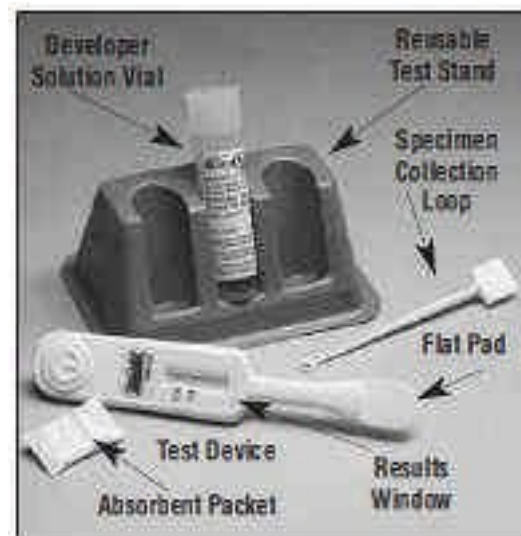
## II. PROCEDURAL INSTRUCTIONS

### 1. PREANALYTICAL

#### KIT CONTENTS AND STORAGE

##### Material Provided

- Divided Pouches, each containing:
  - Test Device (1)
  - Absorbent Packet (1)
  - Developer Solution Vial (1)
- Reusable Test Stands
- Specimen Collection Loops
- Subject Information Pamphlets
- Package Insert
- Customer Letter



## Materials required and available as an accessory to the kit

OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test Kit Controls:

Package contains HIV-1 Positive Control (1 vial, black cap, 0.2 mL), HIV-2 Positive Control (1 vial, red cap, 0.2 mL) and Negative Control (1 vial, white cap, 0.2 mL), and a Package Insert

## Materials required but not provided

- Timer or watch capable of timing 20 to 40 minutes
- Clean, disposable, absorbent workspace cover
- Personnel Protective Equipment
- Biohazard waste container

## For Fingerstick samples the following additional material are required

- Antiseptic wipe
- Sterile lancet to obtain a fingerstick whole blood specimen
- Sterile gauze pads

## STORAGE INSTRUCTIONS

Store unused OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Tests unopened at 2°-27°C (36°-80°F). Do not open the Divided Pouch until you are ready to perform a test. If stored refrigerated, ensure that the Divided Pouch is brought to operating temperature (15°- 37°C, 59°- 99°F) before opening.

## QUALITY CONTROL

### *Built-in Control Features*

The OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test has a built-in procedural control that demonstrates assay validity. A reddish- purple line in the Control (“C”) area of the Result Window indicates that a specimen was added and that the fluid migrated appropriately through the Test Device. The Control line will appear on all valid tests, whether or not the sample is reactive or non-reactive. (Refer to *Test Result and Interpretation of Test Results* section below.)

### ***External Kit Quality Control***

OraQuick ADVANCE® Kit Controls are human plasma-based reagents. The Kit Controls are available separately for use only with the OraQuick ADVANCE® Rapid HIV-1/2 Antibody Test. The Kit Controls are specifically formulated and manufactured to ensure performance of the Test, and are used to verify your ability to properly perform the test and interpret the results. The HIV-1 and HIV-2 Positive Controls will produce a Reactive test result and have been manufactured to produce a very faint Test (“T”) line. The Negative Control will produce a non-reactive test result. (Refer to *Test Result and Interpretation of Test Result* section below.) Use of kit control reagents manufactured by any other source may not produce the required results, and therefore, will not meet the requirements for an adequate quality assurance program for the OraQuick ADVANCE® Rapid HIV-1/2 Antibody Test.

### **Storage Instructions for the OraQuick ADVANCE External Controls**

Store the OraQuick ADVANCE Rapid HIV-1/2 Antibody Test External Kit Controls at 2-8°C (36-46°F). Do not use the Kit Controls beyond the expiration date printed on the outer carton or 56 days beyond opening the vials, whichever date comes first. Open the Kit Control vials only when you are performing tests. Recap and store the vials in their original container at 2-8 °C (36-46°F) after use. Document Use by date (8 weeks out) on controls when opened.

**Dispose of unused portions of opened Kit Control vials after eight (8) weeks.**

### **Materials Provided in External Control Box**

1. One HIV-1 Positive Control- a black-capped vial
2. One HIV-2 Positive Control- a red-capped vial
3. One Negative Control- a white-capped vial
4. Package Insert

### **Materials Required and Provided in the OraQuick ADVANCE Rapid HIV-1/2 Antibody Test Kit**

1. (2) Divided Pouches each containing (1) Test Device, (1) Absorbent Packet, and (1) Developer Solution Vial.
2. Reusable Test Stands
3. Specimen Collection Loops

## **When to perform Kit Controls under the following circumstances:**

- Each new operator prior to performing testing on patient specimens.
- When opening a new test kit lot.
- Whenever a new shipment of test kits is received.
- If the temperature of the test kit storage area falls outside of 2°-27°C (36°-80°).
- If the temperature of the testing area falls outside of 15°-37°C (59°-99°)
- After two consecutive invalid test results on a patient test.
- Whenever a patient result does not correlate with clinical symptoms and when operator/technician deems necessary.

## **2. ANALYTICAL**

### **SET UP YOUR WORKSPACE**

- Gather the materials you will need
- Allow the test kit to come to operating temperature (15°-37°C; 59°-99°F) before use.
- Refer to the External Quality Control section in this procedure to determine when the Kit Controls should be run.
- Cover you workspace with a clean, disposable, absorbent workspace cover.
- Set an OraQuick Advance Reusable Test Stand up on your workspace cover. Use only the stand provided.
- Put on PPE

## CONTROL PREPARATION AND REQUIRED PAPERWORK

Remember to set-up one test at a time when preparing to run external controls. Always run the Negative control first to prevent detectable cross contamination between the negative and positive external control.

1. Remove the external controls from the refrigerator.
2. New lot of control material- Write the date opened on the box of controls (ex: Open Date: 09/03/10).
3. Count 8 weeks (56 days) from date of opening and write that new expiration date (use by date) on box (ex: Use by Date: 10/28/10).
4. Current lot of control material-Check to make sure that the box of controls have not exceeded the 8 weeks use by date or the manufacturer's expiration date.
  - If it has been more than 8 weeks since the box was opened, discard the remaining unused portion in a biohazard waste container.
  - Obtain a new set of controls from the refrigerator and write the current date on the box as the date opened.
5. Check the expiration date on the kit controls.
  - If the kit controls are expired discard them in a biohazard trash container.
  - Check the refrigerator for any more expired kit controls and discard them in a biohazard waste container.
  - If all kit controls are expired then the controls cannot be run. Therefore, patient samples cannot be tested until the external controls have been successfully run using unexpired external controls.
6. Gather all required materials and put on disposable gloves.
7. Cover your workspace with a clean, disposable, absorbent workspace cover.
8. Place an OraQuick ADVANCE reusable test stand on your workspace cover. Use only the stand provided by OraQuick ADVANCE.
9. Open only one test device pouch at a time.
10. Check the expiration date on the pouch.
  - If the test device is expired, discard and use a new test device that has a valid expiration date.
12. Complete Quality Control Log Sheet. This includes current date, lot number of the kit controls, expiration date of the kit controls, lot number of the test device, expiration date of test device, and the temperature of the testing area.
13. Open both chambers of the OraQuick ADVANCE divided test device pouch by tearing at the notches on the top of each side of the pouch.
  - Open only one pouch at a time. To prevent contamination, leave the test device in the pouch until you are ready to use it.
14. Remove the developer solution vial from the pouch.
  - Label the vial either Negative, HIV-1 Positive or HIV-2 Positive, depending on which control you are working with.
  - Hold the vial firmly in your hand. Carefully remove the cap from the developer solution vial by gently rocking the cap back and forth while pulling it off. Set the cap on the workspace cover.
15. Slide the Vial into the top of one of the slots in the Stand. Do not force the vial into the Stand from the front of the slot as splashing may occur.
  - Confirm that the vial is pushed all the way to the bottom of the slot in the Stand.



## EXTERNAL CONTROL TESTING PROCEDURE

1. Open the Negative or HIV-1 Positive or HIV-2 Positive control vial.
2. Insert the round end of an unused specimen collection loop into the corresponding control reagent (Negative or HIV-1 Positive or HIV-2 Positive).
3. Visually inspect the loop to make sure that it is completely filled with the control reagent. **Use separate unused Specimen Collection Loop for each control reagent.**

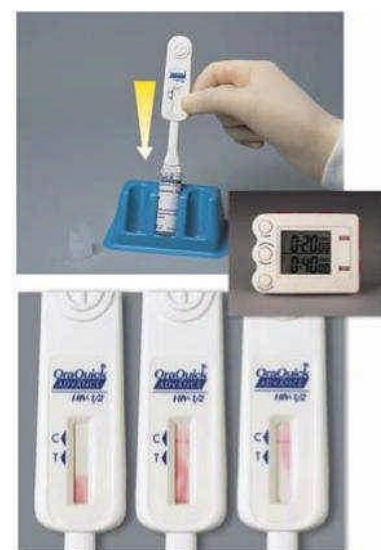


**NOTE: The Kit Control reagents are clear to straw-colored. Do not use if the reagent appears visually cloudy or discolored.**

4. Immediately immerse the control-reagent-filled Specimen Collection Loop in the developer solution inside the Developer Solution Vial.
  - Stir the specimen in the developer solution with the loop.
  - Remove the Specimen Collection Loop from the developer solution vial and discard the used loop in a biohazard sharps container.
  - Remove the Test Device from the Divided Pouch. Do not touch the flat pad. If you touch the flat pad, discard the device and all elements of the opened pouch in a biohazard waste container and start the test from the beginning using a new complete unused pouch containing a vial, device, and absorbent package. A second control sample must be collected.



5. Check to make sure that an absorbent packet is included with the device.
  - If no absorbent packet is present, discard the device and all elements of the opened pouch in a biohazard waste container and start the test from the beginning using a new complete unused pouch containing a vial, device, and absorbent package.
6. Label the device with appropriate external control designation (Negative or HIV-1 Positive or HIV-2 Positive). Do not touch the flat pad of the device. If using an adhesive label, do not cover the two holes on the back of the device.
7. With the result window facing you, insert the flat pad of the device all the way into the Developer Solution Vial containing the control sample. Make sure that the flat pad touches the bottom of the vial. Do not remove the device from the vial while the test is running. Do not move the stand containing the vial and the device during testing.
8. Reseal the external control reagent vial.
9. Set/Start the timer for 20 minutes.
  - Pink fluid will appear and travel up the result window.
  - The pink fluid will gradually disappear as the test develops.
  - Read the results after 20 minutes, but not more than 40 minutes, in a fully lighted area.
  - Write down the result of the test on the Quality Control Log Sheet
10. Dispose of the used developer solution vial, test device, workspace cover and gloves in a biohazard waste container.
11. **Repeat all steps beginning with step 4 of Control Preparation** using the next



external control (Negative or HIV-1 Positive or HIV-2 Positive) and a new, complete, unused pouch containing a developer solution vial, test device, and absorbent package. When completely done with all three controls, put the external control reagent vials back in their original container and store at 36°F to 46°F (2°C to 8°C).



If the Kit Controls for the Negative Control, HIV-1 Positive Control or HIV-2 Positive Control is not as expected, the test should be repeated using a new test device, developer solution vial, and appropriate control specimen. If the test result for any control is not as expected upon repeat testing, discontinue testing and contact OraSure Technologies Customer Support at 1-800-869-3538.

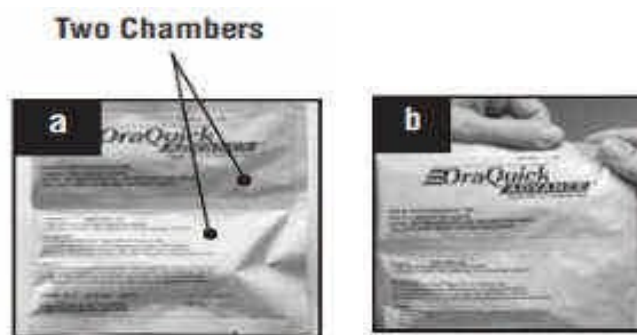
If expected control results are achieved, then you may proceed with running patient samples.

Prior to testing provide the “Subject Information” pamphlet to the person being testing.



## GENERAL TEST PREPARATION

1. Open the two chambers of the OraQuick Advance Divided Pouch by tearing at the notches on the top of each side of the Pouch (*see picture a and b*). To prevent contamination, leave the Test Device in the Pouch until you are ready to use it.
2. Remove the Developer Solution Vial from the Pouch. Hold the Vial firmly in your hand. Carefully remove the cap from the Vial by gently rocking the cap back and forth while pulling it off. Set the cap on your workspace cover.



- Slide the Vial into the top of one of the slots in the Stand. **DO NOT** force the vial into the Stand from the front of the slot as splashing may occur. Makes sure the Vial is pushed all the way to the bottom of the slot in the stand (see picture c).

**NOTE: DO NOT cover the two holes in the back of the Device with labels or other materials. Doing so may cause an invalid result.**

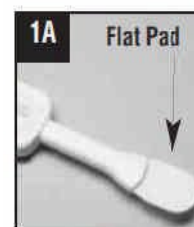


## SPECIMEN COLLECTION AND TESTING PROCEDURE

### ORAL FLUID PROCEDURE

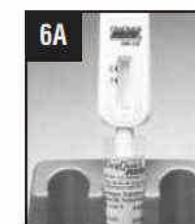
#### STEP 1: COLLECT

- Ensure prior to testing that the subject has not had anything to eat, drink or has chewed gum for at least 15 minutes. Have the subject wait for at least 30 minutes prior to testing if they have used any oral care products.
- Have the person being tested remove the Device from its Pouch. **DO NOT** allow the person to touch the Flat Pad (see picture 1A). Check to make sure that an Absorbent Packet is included with the Device (see picture 2A). If no Absorbent Packet is present, discard the Device and obtain a new Pouch for testing.
- Direct the person to place the Flat Pad above the teeth against the outer gum. Direct the person to gently swab completely around the outer gums, both upper and lower, one time around, using the Flat Pad (see pictures 3A and 4A). **DO NOT** allow the person to swab the roof of the mouth, the inside of the cheek or the tongue. **NOTE:** Both sides of the Flat Pad may be used during this procedure.



#### STEP 2: TEST

- Instruct the person being tested to insert the Flat Pad of the Device all the way into the Vial (see picture 5A). Make sure that the Flat Pad touches the bottom of the Vial. The Result Window on the Device should be facing towards you (see picture 6A).
- Start timing the test (see picture 7A). **DO NOT** remove the Device from the Vial while the test is running. Pink fluid will appear and travel up the Result Window. The pink fluid will gradually disappear as the test develops (see picture 8A). Read the results after 20 minutes but not more than 40 minutes in a fully lighted area.

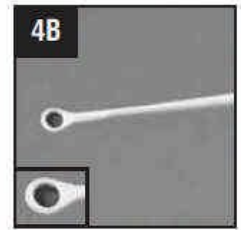
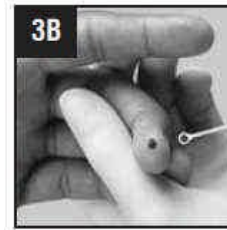


#### 3. Refer to the *Test Result and Interpretation of Test Result*

## FINGERSTICK WHOLE BLOOD PROCEDURE

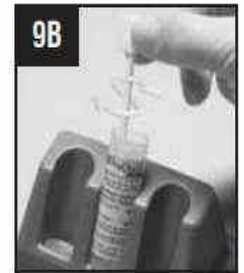
### STEP 1: COLLECT

1. Using an antiseptic wipe, clean the finger of the person being tested. After cleansing the skin puncture site, allow the area to air dry, so the antiseptic action of the alcohol can take effect. Using a sterile lancet, puncture the skin just off the center of the finger pad. Hold the finger downward. Apply gentle pressure beside the point of the puncture. Avoid squeezing the finger to make it bleed (see picture 1B). Wipe away this first drop of blood with a sterile gauze pad. Allow a new drop of blood to form.
2. Pick up an unused Specimen Collection Loop by the thick “handle” end (see Picture 2B). Put the “rounded” end of the Loop on the drop of blood (see picture 3B). Make sure that the Loop is completely filled with blood (see picture 4B). NOTE: If the Loop is dropped or comes in contact with any other surface, discard it in a biohazard waste container. Get a new Loop for the collection of the blood sample.

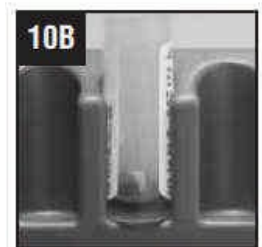


### STEP 2: MIX

1. Immediately insert blood-filled end of the Loop all the way into the Vial (see picture 8B). Use the Loop to stir the blood sample in the Developer Solution (see picture 9B). Remove the used Loop from the Solution. Throw the used Loop in a biohazard waste container.

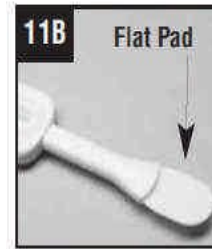


2. Check the Solution to make sure that it appears pink. This means that the blood was correctly mixed into the Solution (see picture 10B). If the Solution is not pink, discard all test materials in a biohazard waste container. Start the test over. Use a new Pouch and a new blood sample.



### STEP 3:TEST

1. Remove the Device from the Pouch. **DO NOT** touch the Flat Pad (see picture 11B). Check to make sure that an Absorbent Packet is included with the Device (see picture 12B). If no Absorbent Packet is present, discard the Device and obtain a new Pouch for testing.
2. Insert the Flat Pad of the Device all the way into the Vial containing the blood sample (see picture 13B). Make sure the Flat Pad touches the bottom of the Vial. The Result Window on the Device should be facing towards you (see picture 14B).
3. Start timing the test (see picture 15B). **DO NOT** remove the Device from the Vial while the test is running. Pink fluid will appear and travel up the Result Window. The pink fluid will gradually disappear as the test develops (see picture 16B). Read the results after 20 minutes but not more than 40 minutes in a fully lighted area.



4. Refer to the *Test and Interpretation of Test Results* Section

### GENERAL TEST CLEAN-UP

1. Dispose of the used test materials in a biohazard waste container.
2. When using gloves, change your gloves between each test to prevent contamination. Throw away the used gloves in a biohazard waste container.
3. Use a freshly prepared 10% solution of bleach to clean up any spills.

### TEST AND INTERPRETATION OF TEST RESULTS

#### Refer to the Result Window on the Test Device

#### NON-REACTIVE

The diagram at the right shows an example of a **Non-Reactive** test result.

A test is **Non-Reactive** if:

a reddish-purple line appears next to the triangle labeled “C” **and** NO line appears next to the triangle labeled “T”.

A **Non-Reactive** test result means that HIV-1 and HIV-2 antibodies were not detected in the specimen. The test is interpreted as **NEGATIVE for HIV-1 and HIV-2 antibodies**. Follow CDC/Department for Public Health guidelines to inform the test subject of the test results and its interpretation.



## REACTIVE

The diagrams at the right show examples of a **Reactive** test result.

A test is **Reactive** if:

- a reddish-purple line appears next to the triangle labeled “C” and
- a reddish-purple line appears next to the triangle labeled “T”. One of these lines may be darker than the other.

NOTE: the test is **Reactive** if a **complete** reddish-purple line appears next to the “T” triangle and next to the “C” triangle, no matter how faint these lines are.



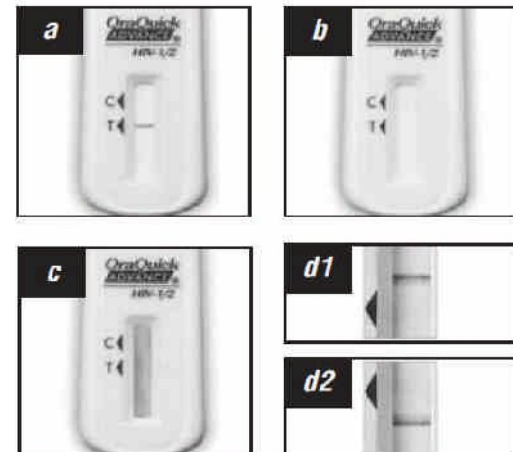
A **Reactive** test result means that HIV-1 and/or HIV-2 antibodies have been detected in the specimen. The test result is interpreted as **PRELIMINARY POSITIVE for HIV-1 and/or HIV-2 antibodies.** Follow CDC/Department for Public Health guidelines to inform the test subject of the test results and its interpretation.

## INVALID

The diagrams at the right show examples of an **Invalid** test result.

A test is **Invalid** if any of the following occurs:

- **NO** reddish-purple line appears next to the triangle labeled “C” (see picture a and b), or
- a red background in the Result Window makes it difficult to read the result after 20 minutes (see picture c), or
- if any of the lines are NOT inside the “C” or “T” triangle areas (see picture d1 and d2)
- any partial line on one side of the “C” or “T” triangle areas



An Invalid test result means that there was a problem running the test, either related to the specimen or to the Test Device. An **Invalid** result cannot be interpreted. **Repeat the test with a new Divided Pouch and a new oral fluid or fingerstick sample. Contact OraSure Technologies Customer Service if you are unable to get a valid test result upon repeat testing. Do not Report Patient Result.**

### **3. POST ANALYTICAL**

#### **REPORTING RESULTS**

Test results are recorded on the patient's medical record by using the CH-12 form. Refer to testing procedure step 4 above. Patient result will be circled to indicate that the test kit built in internal control performed properly (reddish line at "C" area and background clear). Note on CH-12 form the collection site- either oral or fingerstick.

#### **MEDICAL MANAGEMENT**

Follow specific Department for Public Health Core Clinical Service Guide for Medical Management.

#### **WARNINGS**

##### ***For in vitro Diagnostic Use***

- 1. Read the package insert completely before using the product. Follow the instructions carefully. Not doing so may result in inaccurate test results.**
- 2. Before performing testing, all operators MUST read and become familiar with Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and other Blood-borne Pathogens in Health-Care Settings.**
- 3. FDA/Department for Public Health has approved this kit for use with oral fluid, fingerstick whole blood.**
- 4. This test should be performed at temperatures in the range of (15°- 37°C, 59°- 99°F). If stored refrigerated, ensure that the Divided Pouch is brought to operating temperature (15°- 37°C, 59°- 99°F) before performing testing.**
- 5. If the test kit is stored at temperatures outside of ambient temperature (2°- 27°C, 36°- 80°F), or used outside of the operating temperature (15°- 37°C, 59°- 99°F), use the Kit Controls to ensure performance of the test.**
- 6. Individuals infected with HIV-1 and/or HIV-2 who are receiving highly active antiretroviral therapy (HAART) may produce false negative results.**
- 7. Individuals undergoing preventive treatment for HIV may produce false negative results.**

#### **PRECAUTIONS**

##### **Safety Precautions**

- 1. Handle blood specimens and materials contacting blood specimens as if capable of transmitting infectious agents.**
- 2. Do not drink, eat, or smoke in areas where specimens are being handled or testing is being performed.**
- 3. Wear disposable gloves while handling blood specimens and performing testing of blood specimens. Change gloves and wash hands thoroughly after performing each test. Dispose of used gloves in a biohazard waste container.**
- 4. Oral fluid is not considered potentially infectious unless it contains blood. Test Administrators with breaks in the skin (cuts, abrasions, or dermatitis) should wear gloves when performing oral fluid testing. Wash hands thoroughly after performing each oral fluid test and after contact with oral fluid.**

5. Dispose of all test specimens and materials used in the test procedure in a biohazard waste container. Lancets and venipuncture materials should be placed in a puncture-resistant container prior to disposal. The recommended method of disposal of biohazard waste is autoclaving for a minimum of 1 hour at 121°C. Disposable materials may be incinerated. Liquid wastes may be mixed with appropriate chemical disinfectants. A freshly prepared solution of 10% bleach (0.5% solution of sodium hypochlorite) is recommended. Allow 60 minutes for effective decontamination. **NOTE: Do not autoclave solutions that contain bleach.**
6. Wipe all spills thoroughly with a solution of 10% bleach or other appropriate disinfectant. Bleach solutions should be made fresh each day.
7. For additional information on biosafety, refer to “Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and other Blood-borne Pathogens in Health-Care Settings” and “Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis”.

### Handling Precautions

1. Use all Specimen Collection Loops, Test Devices, and Developer Solution Vials only once and dispose of properly (see Safety Precautions). **Do not reuse any of these test components.**
2. Do not use the test beyond the expiration date printed on the Divided Pouch. Always check expiration date prior to testing.
3. Do not interchange Test Devices and Developer Solution Vials from kits with different lot numbers.
4. Avoid microbial contamination and exercise care in handling the kit components.
5. To ensure accurate results, the Test Device must be inserted into the Developer Solution Vial within 60 minutes after introducing the fingerstick whole blood sample.
6. When collecting oral fluid specimens the Test Device must be inserted into the Developer Solution Vial within 30 minutes of collection. A Test Device containing an oral fluid specimen that is not inserted into the Developer Solution Vial within 10 minutes of collection should be either stored on a flat surface or returned to the Divided Pouch after the desiccant has been removed from the Divided Pouch. For a 10-30 minute delay in insertion, return the Test Device containing the oral fluid specimen to the Divided Pouch after the desiccant has been removed from the Divided Pouch. Ensure that the Divided Pouch containing the Test Device is kept in a horizontal position until the Test Device is inserted into the Developer Solution Vial.
7. Adequate lighting is required to read a test result.

### LIMITATIONS

1. The OraQuick Advance Rapid HIV-1/2 Antibody Test must be used in accordance with the instructions in the package insert to obtain an accurate result.
2. Reading test results earlier than 20 minutes or later than 40 minutes may yield erroneous results.
3. This test is approved by FDA/Department of Public Health for oral fluid and fingerstick whole blood.
4. Individual infected with HIV-1 or HIV-2 who are receiving highly active antiretroviral therapy (HAART) may produce false negative results.
5. Individuals undergoing preventive treatment for HIV may produce false negative results.

6. Clinical data has not been collected to demonstrate the performance of the OraQuick Advance Rapid HIV-1/2 Antibody Test in persons under 12 years of age.
7. A reactive result using the OraQuick Advance Rapid HIV-1/2 Antibody Test suggests the presence of HIV-1 and/or HIV-2 antibodies in the specimen. OraQuick Advance Rapid HIV-1/2 Antibody Test is intended as an aid in the diagnosis of infection with HIV-1 and/or HIV-2. AIDS and AIDS-related conditions are clinical syndromes and their diagnosis can only be established clinically.
8. For a reactive result, the intensity of the test line does not necessarily correlate with the titer of antibody in the specimen.
9. A non-reactive result does not preclude the possibility of exposure to HIV or infection with HIV. An antibody response to recent exposure may take several months to reach detectable levels.
10. A person who has antibodies to HIV-1 or HIV-2 presumed to be infected with the virus, except that a person who has participated in an HIV vaccine study may develop antibodies to the vaccine and may or may not be infected with HIV. Clinical correlation is indicated with appropriate counseling, medical evaluation and possibly additional testing to decide whether a diagnosis of HIV infection is accurate.
11. See package insert for interfering substances and unrelated medical conditions that could impact testing.

### **PROBLEM SOLVING**

If the correct control results are not obtained, do not report patient results. For Technical Assistance Contact Technical Services at 1-800-672-7873 or 1-800-869-3538.

### **III. REFERENCES**

OraQuick Advance Rapid HIV-1/2 Antibody Test Package Insert, OraSure Technologies, Inc, Bethlehem, PA 18015, USA, rev. 09/12

OraQuick Advance Kit Controls Package Insert, OraSure Technologies, Inc, Bethlehem, PA 18015, USA, rev. 08/12

Centers for Disease Control and Prevention (CDC), Department for Health and Human Services, *“Quality Assurance Guidelines for Testing Using Rapid HIV Antibody Waived Under the Clinical Laboratory Improvement Amendments of 1988”*, [http://www.cdc.gov/hiv/topics/testing/resources/guidelines/qa\\_guide.htm](http://www.cdc.gov/hiv/topics/testing/resources/guidelines/qa_guide.htm), July 24, 2007

### **IV. AUTHOR**

Linda Dailey MT (ASCP) January 2011

### **V. PROCEDURE POLICY, APPROVAL AND REVIEW PROCESS**

1. The procedure is to be placed in the SOPM.
2. Each procedure will be initially reviewed and approved with signature by the Director prior to implementation.
3. Each procedure will be reviewed annually and as needed for necessary revision. Any modification will be reviewed and approved as stated in #2 above.

4. Implementation of new or revised procedures must be communicated to all testing personnel prior to the implementation date. The Director must document that each of the testing personnel (by individual name) have been made aware of the procedure changes, revision implementation date and been trained as necessary.
5. Any associated logs, specimen collection instructions or other documents related to the procedure change must be initiated.
6. Each procedure must have a master file. The master file serves as the documented history of the procedure, showing all revisions and the dates used and discontinued or retired.
7. The master file must be maintained for a least two (2) years from last date used.

## VI. APPENDIX

OraQuick Advance Rapid HIV-1/2 Antibody Test QC log

## VII. PROCEDURE HISTORY

<i>Revision Date:</i>	<i>Initials:</i>	<i>Pages Affected:</i>	<i>Description of Change(s):</i>
4/23/2012	LMD	P10	Added into Step 1 Oral fluid procedure the stipulations not food, drink, gum or oral care products.
4/23/2012	LMD	P11	Added additional comments to Step 1 Fingerstick whole blood collection procedure on cleansing of puncture site.
3/5/2013	LMD	P11	Change Public Health Practice Reference to Core Clinical Service Guide.
5/10/2013	LMD	P3	Changed temperature range from 35-80°F to 36-80°F
5/10/2013	LMD	P4	Changed control storage from 35-46° to 36 -46°
5/10/2013	LMD	P5	Update intervals to perform QC- take out additional sites
5/10/2013	LMD	P6	Take out to let external controls come to room temperature before use
5/10/2013	LMD	P6	Take out use of safety glasses or splashguard in #8 and #9.
5/10/2013	LMD	P7	Take out reference to safety glasses in #15
5/10/2013	LMD	P7	Take out instructions if any portion of developer solution spilled in #15 and External Control Testing Procedure #4.
5/10/2013	LMD	P8	Update temperature #11 from 35- 36°.
5/10/2013	LMD	P13	Update Note: the test is Reactive if <b>a complete</b> reddish-purple
5/10/2013	LMD	P13	Invalid test- add bullet "any partial line on one side of the "C" or "T" triangle area.
5/10/2013	LMD	P14	Update temperature in #5 from 35° to 36°
5/10/2013	LMD	P14	Add #7 to Warnings- Individuals undergoing preventive treatment for HIV may produce false negative results.
5/10/2013	LMD	P15	Add to #4- Test personnel and glove use
5/10/2013	LMD	P16	Limitations- add #5 Individual undergoing preventive treatment for HIV may produce false negative results.
5/10/2013	LMD	P16, 17	Update reference revisions
5/10/2013	LMD	P19	Update QC form for control intervals

# OraQuick Advance Quality Control Log

**\*\*Begin a new log with each new lot number of testing kits\*\***

Reagent Name: OraQuick Advance      Kit Lot #: \_\_\_\_\_ (from box)      Exp. Date: \_\_\_\_\_  
 Lot #: \_\_\_\_\_ (from Divided Pouch)      Exp. Date: \_\_\_\_\_  
 Control Name: OraQuick Advance      Lot #: \_\_\_\_\_ (from box)      Exp. Date: \_\_\_\_\_

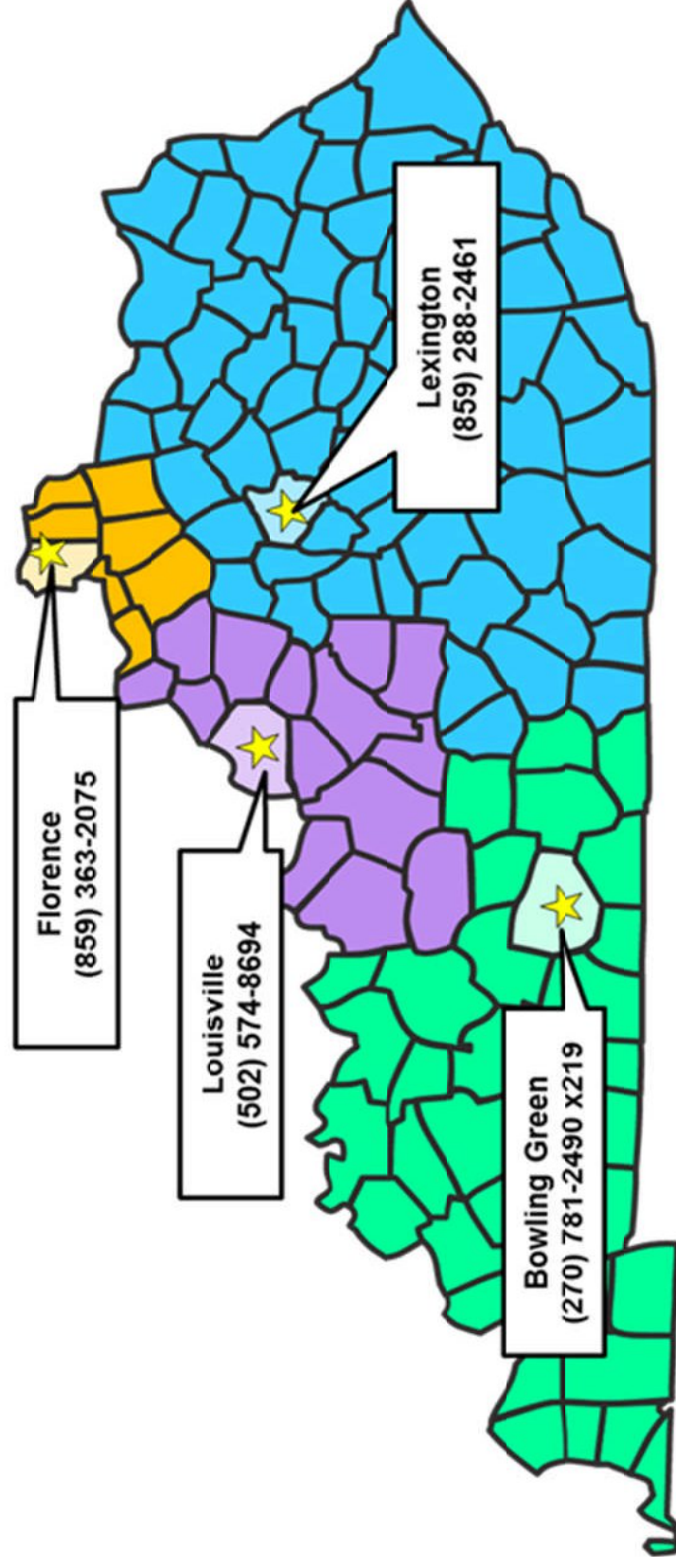
External Controls: OraQuick Advance	Lot # (on bottle of control material)	Mfg Exp Date	Date Opened	Use by Date (8 weeks after opening)
Negative				
Positive HIV-1				
Positive HIV-2				

Date	Time	Negative Control		Positive HIV -1 Control		Positive HIV-2 Control		P/F	Tech	Comments- Corrective Actions
		✓ Internal control ("C" line present- background clear)	Result	✓ Internal control ("C" line present- background clear)	Result	✓ Internal control ("C" line present- background clear)	Result			

**Control Interval:** **1.** With each new operator. **2.** New test kit lot **3.** New shipment of test kits. **4.** When temperature of the test storage area falls outside 2°C -27°C. **5.** When the temperature of the testing area falls outside 15°C -37°C. **6.** After 2 consecutive invalid test result on a patient.. **7.** Whenever a patient result does not correlate with clinical symptoms. **8.** When operator deems necessary.

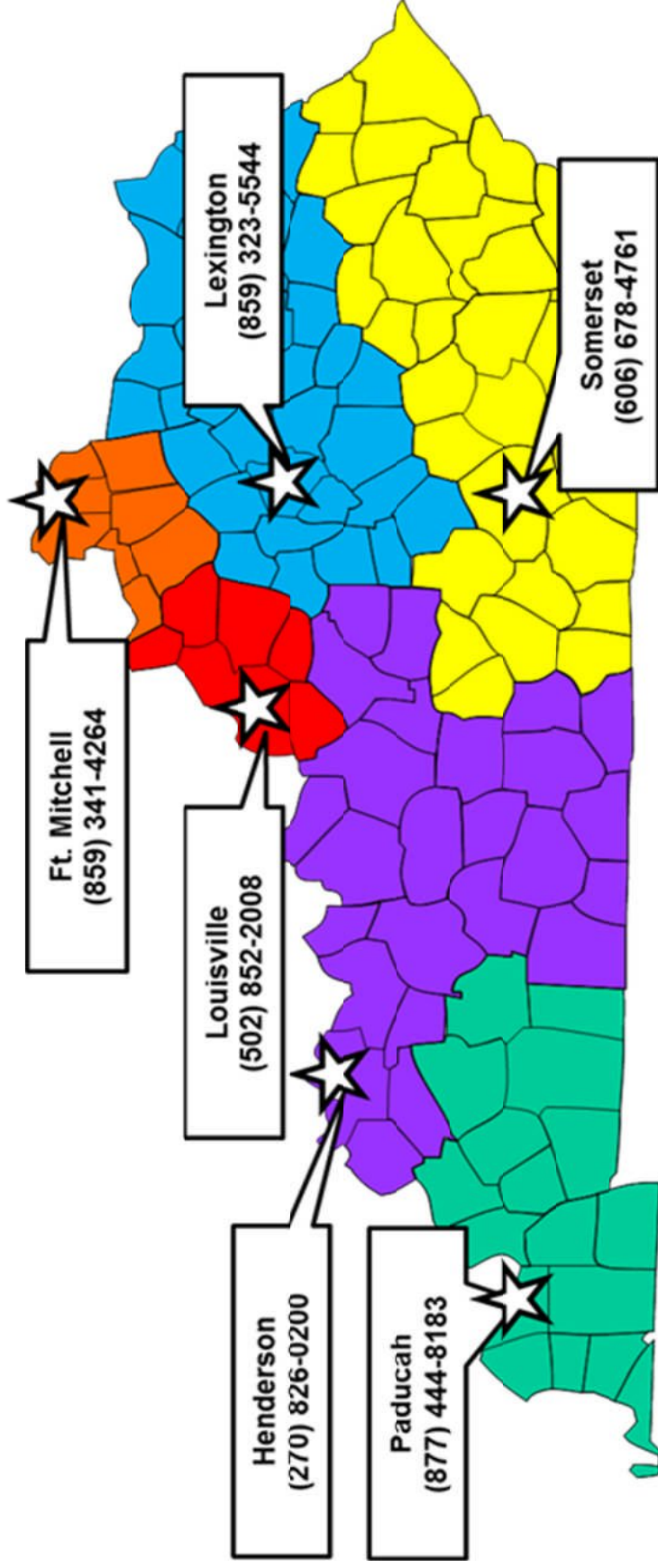
Supervisor Review \_\_\_\_\_ Date \_\_\_\_\_

## Kentucky Disease Intervention Specialists



STATE OFFICE (STD Control Section): (502) 564-4804

## Care Coordinator Regions and Centers



STATE OFFICE (HIV Services Section): (502) 564-6539